A RELIABILITY AND CRITERION-RELATED VALIDITY STUDY OF BIOELECTRIC IMPEDANCE ANALYSIS (BIA)

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by

Dolores P. Iannone

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Dolores P. Iannone

Approved by Committee:

Linda Brady, Ph.D., Chair

Susan Johnson, M.S.N.

William Wickemeyer, M.D.

Ronald B. Kluza, Ph.D.
Dean of the College of
Pharmacy and Health Sciences

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An abstract of a Thesis by
Dolores P. Iannone
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Drake University
Advisor: Linda Brady

The problem. The purpose of this study was to determine the reliability and criterion-related validity of bioelectrical impedance analysis (BIA) as a method of monitoring fluid changes in congestive heart failure (CHF) patients undergoing diuresis.

Procedure. Thirty hospitalized CHF patients undergoing diuresis were measured with BIA and weighed prior to the administration of a diuretic and 24 hours thereafter. An intake-output (I-O) record was obtained during this time period. Daily body weights (BWT) and I-O records served as the criteria by which to compare the BIA measurements. A reliability coefficient on 10 normal age-matched subjects was obtained using a test-retest approach.

Findings. Statistically significant relationships were found between BIA total body water (TBW) and BWT, $r = .729$ ($p<.001$) and BIA-TBW and I-O, $r = .745$ ($p<.001$) when the average of right and left TBWs was obtained. The BIA-TBW taken from the non-dominant side of the body also resulted in strong correlations with BWT and I-O, $r = .648$ ($p<.001$), $r = .704$ ($p<.001$) respectively. The BIA-TBW taken from the dominant side correlated well with BWT, $r = .515$ ($p = .001$), but did not correlate significantly with I-O, $r = .451$ ($p = .024$). A reliability coefficient of .9984 was obtained.

Conclusions. The results of this study indicate that BIA is a reliable technique and comparable to the traditional methods of DBW and I-O in fluid assessment of CHF patients undergoing diuresis.

Recommendations. Repeating the study with the inclusion of reliability and validity determinations of the criteria standards will improve the integrity of the study. In addition, further refinement of BIA technology identifying hydration abnormalities and using the average of right and left BIA-TBWs will result in more accurate data in patient populations.

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INTRODUCTION

Statement of the Problem

The purpose of the present study was to determine validity and reliability of bioelectrical impedance analysis (BIA) as a method of monitoring fluid changes in congestive heart failure patients (CHF) undergoing diuresis. Monitoring fluid changes is a primary and major responsibility of the nurse and demands accuracy and timeliness of information. To date, the standard and conventional methods of assessment of fluid status utilized by nurses are to obtain daily body weights (DBW) and intake-output (I-O) records. Bioelectrical impedance analysis is a new technology that provides a rapid, precise, and noninvasive means of assessing total body water (TBW) and other body composition data in normal subjects. Therefore the specific problem for this methodological study was "Is BIA a valid and reliable method for monitoring fluid changes in CHF patients treated with diuretics?"

Background

In spite of the primary and major role nurses play as monitors and assessors of the fluid status of CHF patients undergoing diuresis, the method of making such assessments have remained unchanged, unchallenged, and elementary. The conventional and standard methods have been to record DBW and to maintain an intake-output record that is as accurate as possible. Monitoring fluid changes is a nursing function that demands accuracy and timeliness of information. However, intake-output information may not be timely enough and the obtaining of a body weight potentially compromises an already fatigued patient.

Diuretics are widely used in the therapy of congestive heart failure. The objective is to increase the elimination of sodium and water. Sodium and water retention is a result of one of several compensatory mechanisms in CHF meant to maintain adequate cardiac output. Fluid management during diuresis, therefore, assumes a prominent role in diuretic therapy. Overaggressive diuresis may lead to eventual systems failure, while on the other hand, inadequate diuresis may lead to circulatory overload, dilation of the heart, and acute pulmonary edema. Early detection of

this life-threatening but oftentimes preventable fluid imbalance is the goal in monitoring the fluid status of CHF patients undergoing diuresis.

Bioelectrical impedance analysis is a new technology that promises to offer a rapid, precise, and noninvasive assessment of TBW and other body composition data. The increasing interest by the scientific community in body composition data as it pertains to nutrition-obesity studies led to the research and development of the RJL BIA-103. The BIA is an instrument that can measure the components of total body impedance which are defined as resistance and reactance. Resistance can be equated to the total body water volume (intracellular mass + extracellular mass). In the body, lean tissue is considered highly conductive because of its water and electrolytes; therefore, offering low resistance. Reactance can be equated to the quantity of cell membrane barriers which separate intracellular and extracellular volumes. Cell membranes are three-layered structures; a middle layer consisting of a non-conductive material (high resistance) sandwiched between two layers of conducting protein molecules. This impedance data was obtained by placing two electrodes each on the wrist and ankle.

This test required less than three minutes of the subject's time. The results of the test, that is resistance and reactance data, together with other information such as height and weight were entered into a computer program which yielded the following information: percentage body fat, lean body mass, total body water, optimal weight, and estimated basal metabolism. For the purposes of this study total body water (TBW) was the only datum needed.

Establishing reliability and validity of newly developed measuring instruments is essential and was the focus of this study. Lukaski, Bolonchuk, Hall, & Siders (1986) have developed a model relating conductance to fat free mass (FFM), TBW, and potassium. Their studies with radioisotope dilution techniques have shown strong inverse relationships between FFM and resistance. Other results generated by their research have shown strong and direct relationships between BIA technology and hydrodensitometry. Hydrodensitometry is a widely used technique for determining body fat and FFM requiring healthy subjects to be submerged in a tank of water.

Radioisotope dilution studies are among the most sophisticated methods utilized to assess body

composition. These studies require highly trained scientists and expensive equipment that exist only in large medical research centers. Kushner and Schoeller (1986), in a correlational study comparing BIA measurement with deuterium isotope dilution measurement, found a strong and direct correlation ($r = .97$).

Studies demonstrating the reliability and validity of BIA as a method for assessing body composition in normal healthy subjects are comprehensive (Gundersen, & Shen 1966; Kushner, & Schoeller, 1986; Lukaski, et al., 1986; Segal, Gutin, Preston, Wang, & Van Itallilie, 1985; Twyman, & Liedtke, 1987). Similar studies with varying patient populations are beginning to proliferate. Examples of patient populations that have been measured with the BIA include the elderly (Hughes & Evans, 1987), amputees (Vettorazzi, Barillas, & Pineda, 1987), in vitro studies simulating surgical patients with electrolyte imbalances (Schloerb, Guriun, Lord, Winiarski, & Casey, 1986), children with infantile diarrheal disease (Molina, Arango, Pineda, & Solomons, 1987), hemodialysis patients (Spence, Baliga, Nyboer, Seftick, & Fleischmann, 1979), fluid retention studies in burn

patients comparing BIA with intake-output (Carlson, Fegelman, Finley, Miller, Jones, Richards, & Alkire, 1986); and, one study by Shellock and Amin (1986) measuring six CHF patients before and after diuresis. Shellock and Amin demonstrated a highly significant ($p.<.01$) loss in TBW and percentage body water in CHF patients after diuresis and concluded that the BIA can be used as a method for assessing fluid status in CHF undergoing diuresis.

It has been shown that TBW measured with radioisotope dilution and the BIA tend to overestimate TBW loss (Nyboer & Sedensky, 1974). A possible explanation of this occurrence is that both BIA and radioisotope dilution techniques are highly sensitive and, therefore, detect more subtle changes.

It must be noted that there is no direct value by which to compare the validity of BIA. Cadaver dissection and tissue analysis are the only direct methods of body composition assessment. Some scientists would argue that radioisotope dilution techniques approximate a direct method of assessment, and as mentioned previously, BIA has correlated strongly with this method. It is important that researchers continue to pursue BIA reliability and

validity studies in order to determine the reliability and validity of the BIA method. The purpose of this investigation was to demonstrate a strong and direct relationship between BIA with daily body weights and intake-output records of hospitalized CHF patients undergoing diuresis. This was a criterion-related validity study. Criterion-related validity is the degree to which scores on an instrument (BIA) are correlated with some external criteria (DBW and I-O) (Polit & Hungler, 1985). Daily body weights and I-O records were the selected criteria because they are the conventional and standard methods used by nurses to assess fluid changes.

A test-retest approach was utilized to generate a reliability coefficient. Ten normal age-matched subjects were measured twice for two reasons: First to document that the BIA machine used for this study gives reliable results on the same patient and secondly, to establish a normal baseline.

This study is relevant to nursing because nurses have a primary and major responsibility in monitoring the fluid changes that occur in CHF patients undergoing diuresis. Accurate and timely information is essential. Bioelectrical impedance analysis offers the

potential of upgrading the accuracy and timeliness of information and therefore directly upgrading the quality of nursing care.

Description of Variables

Independent Variable

The independent variable of this study was the method of measuring fluid changes. The three methods were: (a) RJL BIA-103, (b) daily body weight, and (c) intake-output record.

1. RJL BIA-103. The BIA system is conceptually an integration of electronic and computer software technologies that can be applied to body composition analysis for fluid balance monitoring, nutritional assessment, and monitoring of weight loss and gain regimes. It is a rapid, relatively inexpensive, safe, noninvasive, portable technique which requires minimal special training of the operator and causes virtually no inconvenience to the subject.

The RJL system uses a tetrapolar electrode configuration. Color-coded electrodes were positioned on the dorsal surfaces of the hands and feet. The subject laid fully clothed, except shoes and socks, in a supine position. A harmless 50 KHz current was

introduced into the deep tissue of the subject via two electrodes. The second pair of electrodes measured the electrical impedance. Using a sophisticated computer program, the system, in less than three minutes per subject, computed and generated a print-out of percentage body fat, lean body mass, body fat weight, TBW, optimal weight, and estimated basal metabolism.

2. A protocol was followed to obtain body weight.

3. Standard operative procedure was followed to obtain intake-output records.

Dependent Variables

The dependent variables of this study were the measurements of fluid changes. These measurements were expressed as follows:

1. TBW measured by the BIA was expressed in liters.

2. Body weight measured by a health o meter portable stand-up scale was expressed in kilograms.

3. Fluid output measurements obtained by intake-output records were expressed in liters.

Statement of Assumptions

Assumptions are basic principles that are accepted as being true on the basis of logic or reason, without proof or verification. Basic assumptions underlying this study were as follows:

1. Daily body weights and intake-output records offer the nurse a reliable and valid method of assessing the fluid status of his/her patient.

2. The living organism consists of intracellular and extracellular fluids partitioned by cell membranes. The intra- and extracellular fluids act as electrical conductors while cell membranes are the reactive elements which behave as electrical condensers or capacitors.

3. Body composition assessment is subject to a degree of uncertainty. The degree of accuracy needed in body composition assessment is relative to the degree of practicality of purpose for its intended clinical application.

4. The quality of nursing assessments are upgraded with the development of technology that increases precision and timeliness of information.

Research Hypothesis and Rationale

Ho: There will be no relationship between the BIA method of monitoring fluid status in CHF patients undergoing diuresis and daily body weights and intake-output records, the standard methods of monitoring fluid status.

Ha: There will be a strong positive relationship between the BIA method of monitoring fluid status in CHF patients undergoing diuresis and daily body weights and intake-output records, the standard methods of monitoring fluid status.

Bioelectrical impedance analysis arose from the increasing demand for more accurate body composition data in obesity-nutrition studies. The BIA has since then evolved to include body composition analysis for fluid balance monitoring.

The BIA promised to offer a simple, rapid, precise, and noninvasive indicator of TBW and other body composition data. It was thought to provide with feasibility and accuracy information similar to that obtained from radioisotope dilution studies and other sophisticated methods.

The studies to date on healthy, normal individuals indicated that BIA was a valid and reliable instrument for the assessment of TBW, lean body mass, and body fat. Recent clinical trials on various patient populations strongly suggested that the BIA method was a reliable and valid instrument for monitoring fluid balance and might have been appropriately applied to the clinical setting.

It was postulated that the BIA method was as valid and reliable an indicator of fluid status as were daily body weights and intake-output records, the standard and conventional methods of monitoring fluid status utilized by nurses. Therefore, the underlying rationale for this study was that daily body weights and I-O records were the appropriate criteria by which to determine the validity of BIA as a method for improving the nurse's ability to monitor fluid status of CHF patients undergoing diuresis.

Chapter II

LITERATURE REVIEW

In the following section, literature related to the area of bioelectrical impedance analysis (BIA) and its potential usefulness in monitoring fluid changes will be reviewed. The review will begin with a brief discussion about congestive heart failure (CHF) and the life-threatening but preventable fluid imbalances inherent in this disease process. The current method of monitoring fluid changes in CHF patients undergoing diuresis, essentially intake-output records and daily body weights, will be described in detail followed by an explanation of the underlying concepts and principles of bioelectrical impedance as it relates to assessing body composition. Other methods currently used to assess body composition as well as serve as criteria by which to compare BIA are mentioned. A comprehensive review of available clinical trials describing efforts to establish its reliability and validity both in healthy and ill populations is offered, depicting its potential clinical usefulness. This review will conclude by identifying the

shortcomings in BIA research conducted to date, as well as demonstrate the need for this study.

Congestive Heart Failure

Heart failure is "that condition in which the heart is no longer able to pump an adequate supply of blood in relation to the venous return and in relation to the metabolic needs of the tissues of the body at that particular moment" (Schlant, 1978, 532). Heart failure has been called the final common pathway of heart disease in that all kinds of heart disease will eventually result in some form of heart failure (Beland & Passos, 1981).

Congestive heart failure is that state in which abnormal circulatory congestion occurs as the result of heart failure. This abnormal circulatory congestion is a result of one of the several compensatory mechanisms triggered by the decreased cardiac output of heart failure. Compensatory mechanisms preserve cardiac output but also produce many of the congestive signs and symptoms. The particular mechanism seen in CHF is the retention of sodium and water by the kidneys. Its purpose is to restore adequate volume to the circulation and develops chronically in congestive

heart failure patients (Schlant, 1978). When this is present for any length of time, there is usually transudation of fluid from the capillaries into the interstitial spaces of both the pulmonary and systemic circulation. Symptomatology is reflected as pulmonary edema and generalized edema respectively.

> It is useful to think of heart failure as a pathologic continuum usually initiated by a cardiac disorder progressing in severity from ventricular dysfunction alone to ventricular dysfunction with congestive symptoms and a normal cardiac output at rest and on to persistence of congestive symptoms with overt failure of the pump function of the heart" (Spann & Hurst, 1978, 565).

The primary objective of therapy in all instances of heart failure is to increase the capacity of the heart to adapt or respond as efficiently as possible to the demands made on it. Therefore, fluid management in congestive heart failure (CHF) patients treated with diuretics becomes a major therapeutic intervention of this irreversible process. This intervention is meant to achieve palliation of the process in the absence of a cure. Monitoring fluid changes during diuresis was the problem addressed by this study.

Heart failure causes the kidneys to function abnormally and leads to sodium and water retention, weight gain, edema, visceral congestion, and increased venous pressure. Diuretics are widely used in the therapy of heart failure to increase elimination of sodium and water. "Diuretics are drugs given to increase the flow of urine. The purpose of a diuretic is to increase the net loss of water, and to achieve this there must also be loss of sodium" (Bergersen & Krug, 1966, 530). Diuretics also increase the effectiveness of digitalis, the foremost therapeutic intervention in CHF, by decreasing circulatory blood volume. "Diuretics are eventually needed in most patients with heart failure. Diuretics may reduce and prevent the visceral congestion and peripheral edema, with related symptoms associated with heart failure" (Spann & Hurst, 1978, 594).

Monitoring Fluid Changes

The concept of fluid balance is most important. Fluid imbalance in the cardiac patient is both life threatening and preventable. For example, hypovolemia in the cardiac patient may be the result of over aggressive diuretic therapy. "If left uncorrected,

hypovolemia may result in serious hemodynamic depression, diminished perfusion of other vital organs, and eventual systemic failure of those organs" (Watson, 1987, 799). On the other hand, inadequate diuresis may result in hypervolemia which is characterized by "increased venous pressure and venous return and reflex venoconstriction that is uncompensated and increase in stroke volume" (Watson, 1987, 800). Hypervolemia is soon followed by dilation of the heart and increased capillary pressure. Dilation of the heart increases afterload, which is increased resistance to ventricular emptying, and the increased capillary pressure results in edema. Nursing observations and close monitoring are therefore essential in the early detection of fluid imbalances.

Although I-O and DBW are the most common and conventional methods of assessing fluid changes there are other methods available to the nurse. The identification of edema is a prime example. it is important to note, however, that edema is not usually apparent in the adult until the retention of five to ten pounds of excess fluid. "Pitting edema, a phenomenon manifested by a small depression after one's finger is pressed over an edematous area and then

removed is not evident until at least a 10% increase in weight has occurred" (Methany, 1984, 35). This fact, plus the subjective nature of describing degrees of edema, render it untimely and imprecise in monitoring fluid changes in patients receiving diuretic therapy. There are numerous other methods of assessing fluid status. Urine volume and concentration, skin and tongue turgor, thirst, pulse, respirations, blood pressure, neck and hand vein distention are examples. Though they are valid as additional sources of information their precision is questioned because of their subjective nature. Comparison of intake and output records and daily body weights were therefore selected to serve as criteria by which to monitor fluid changes.

An accurate measurement of the intake of fluid and output of urine is essential during the early days of treatment. Many serious fluid balance problems can be averted by maintaining a careful vigil on patient intake and output and keeping accurate records. Totals for several consecutive days should be compared. Methany (1984) outlines parameters to follow when measuring intake and output:

1. Intake should include all fluids taken in the gastrointestinal route, including foods that are liquid at room temperature, such as gelatin. Of course, fluids gained by the parenteral route must be included.
2. Output should include urine, vomitus, diarrhea, drainage from fistulas, and drainage from suction apparatus. Perspiration should be noted and its amount estimated. The presence of prolonged hyperventilation should also be noted, since it is an important route of water-vapor loss. Drainage from lesions should be noted and estimated.
3. The intake and output record should include the time of day and the type of fluid gained and lost. This information is necessary in planning therapy (p. 30).

Methany (1984) summarizes common sources of error in intake and output measurement:

> Failure to communicate to all members of the staff which patients require intake and output measurements. This may result in discarded body fluids or intakes not recorded, making the entire record inaccurate.

Failure to explain the need for recording all oral fluids to the patient and his family.

Failure to instruct the ambulatory patient to use a bedpan, urinal, or other collecting device for voiding and to save the specimen until it can be measured and recorded.

Failure to measure fluids that can be directly measured because it takes less time to guess at their amounts.

Failure to designate the specific volume of glasses, cups, bowls, and other fluid containers used in the hospital. Each person may ascribe a different volume to the same glass of water.

Well-meaning intentions to record a drink of water or an emptied urinal at a later, more convenient time are often forgotten.

Failure to estimate "uncaught" vomitus or incontinent urine; frequently are recorded as lost specimens with no mention as to the approximate volume.

Failure to measure sips of water. A sip of water, or mouth rinsing, if repeated often, might add up to as much as 1000 ml/day.

> Failure to consider that parenteral fluid bottles are overfilled a liter bottle may actually contain 1100 ml; A 500 ml bottle may contain as much as 600 ml.
>
> Failure to record the amount of solution used to irrigate tubes and the amount of fluid withdrawn during irrigation.
>
> Failure to estimate fluid lost as wound exudate, drainage from a large decubitus can be extensive.
>
> Failure to estimate fluid as perspiration. A necessary linen change may represent as much as a liter of perspiration (p. 30).

Daily weighing of patients undergoing diuresis is of great clinical value because accurate body weight measurements are much easier to obtain than accurate intake-output measurements. Also, rapid variations in weight closely reflect changes in body fluid volume.

> The use of body weight as an accurate index of fluid balance is based on the assumption that the patient's dry weight remains relatively stable. Even under starvation conditions, an individual loses no more than one third to one-half pound of dry weight per day (Methany, 1984, 35).

However, it is the experience of this investigator that weighing patients oftentimes is not an easy and efficient activity for the nursing staff. **Hospitalized** CHF patients are easily fatigued and compromised. If the patient is obese or requires the use of a bed scale, more than one person on the staff is needed to accomplish the task. Variables such as clothing, time of weighing, and scale used may confound the result.

Methany (1984), delineates facts about volume deficit and volume excess:

> Rapid loss of 2% total body weight indicates mild fluid volume deficit.
>
> Rapid loss of 5% total body weight indicates moderate fluid volume deficit.
>
> Rapid loss of 8% or more of total body weight indicates severe fluid volume deficit.
>
> Rapid gain of 2% total body weight indicates mild fluid volume excess.
>
> Rapid gain of 5% total body weight indicates moderate fluid volume excess.
>
> Rapid gain of 8% or more total body weight indicates severe fluid volume excess.
>
> A rapid gain of 1 kg (2.2 lbs) of body weight is approximately equivalent to the gain or loss of 1 liter of fluid (p.37).

According to Methany (1984) the following practices should be followed in weighing patients:

1. Use the same scale each time. There are significant variations among scales.
2. Measure weight in the morning before breakfast and after voiding.
3. Be sure the patient is wearing the same or similar clothing each time. **Be sure that** it is dry (p. 37).

Comparing daily weights enables the physician to appraise the effect of treatment on fluid loss. Whether the fluid loss is beneficial or harmful is determined by other clinical observations.

> When the patient has chronic heart failure and is attempting to maintain his weight at a 'dry' level, a daily weight may be of considerable value in ascertaining the dosage--and interval of time between doses--of diuretic agents employed. The objective is to cause no harm and to maintain a dry weight with the smallest amount of diuretic agent (Spann & Hurst, 1978, 594).

Bioelectrical Impedance Analysis (BIA)

In 1981, RJL Systems commercially pioneered a new method of body composition assessment through the measurement of tissue bioelectrical impedance. the goal was to provide a rapid, precise, accurate, and noninvasive means of assessing TBW, lean body mass (LBM), and body fat to meet the growing demand for body composition data. "It was originally introduced in 1982 to measure hydration status of mountain climbers in high altitude, cold weather environment on Mt. McKinley" (Mills & Rau, 1983, 25).

A tetrapolar configuration is used. Four electrodes are attached to the dorsal surfaces of the right hand and foot of the subject who lays fully clothed, except shoes and socks, in a supine position. A harmless 50 KHz current (800 microamps maximum) is introduced into the deep tissue of the subject via two electrodes. The second pair of electrodes measures the electrical impedance. Phase sensitive electronics quantitate the impedance to the flow of current into the geometric components of resistance (R) and reactance (Xc). Using a sophisticated computer program, the system, in less than three minutes per subject, computes and generates a print-out of the following

information: percentage and weight of body fat, percentage and weight of lean body mass, percentage and liters of total body water, optimal weight and body fat, and estimated basal metabolism (Twyman & Liedtke, 1987).

A basic description of bioelectrical impedance is offered by Twyman and Liedtke (1987):

> A complex impedance measurement consists of resistance and reactance. All substances, with the exception of superconductors, offer resistance to the flow of an electric current. In the body, highly conductive lean tissues contain large amounts of water and conducting electrolytes, and represent a low resistance electrical pathway. Fat and bone, on the other hand, are poor conductors or a high resistance pathway with low amounts of fluid and conducting electrolytes.
>
> Reactance, also known as capacitive resistance, is the opposition to the flow of electric current caused by capacitance. By definition, a capacitor consists of two or more conducting plates separated from one another by an insulating, or non-conductive material, and used to store charge. In the body, the cell membrane

> consists of a layer of non-conductive lipid material sandwiched between two layers of conductive protein molecules. The structure of cell membranes makes them reactive elements which behave as capacitors when exposed to an electrical current.
>
> Theoretically, reactance is a measure of the quantity of cell membrane capacitance and an indication of the quantity of intracellular or body cell mass. Whereas body fat, TBW, and extracellular water offer resistance to electrical current, only cell membranes cause reactance (pp. 12-14).

Body composition is currently estimated by a number of different techniques including: hydrostatic weighing, anthropometry (MAMC, TSF, BW), radiographic analysis, total body potassium (K40), densitometry, total body neutron activation, tomography, ultrasound, total body electrical conductivity (TOBEC), and TBW measurements from the dilution of specific substances such as deuterium oxide, tritium oxide, antipyrine, and oxygen 18. Many of these techniques require expensive and sophisticated equipment and highly trained personnel and therefore tend to be limited to a

university or medical center setting. Others, such as the anthropometric techniques, especially skinfold measurements, do not hold up against scientific scrutiny and are inappropriate in the critical care setting.

"BIA is one method of assessing body composition which utilizes precision and sensitivity in tracking significant changes in short periods" (Bencich, Twyman, & Fierke, 1986, p. 97). The BIA method requires minimal subject cooperation or operator training and can be applied to any setting.

In summary, monitoring fluid changes in CHF patients undergoing diuresis continues to be a primary responsibility of the nursing staff. The utilization of conventional methods of assessment such as intake and output records and daily body weights provide valid but often untimely and imprecise information. The utilization of the BIA offers a simple, noninvasive, and precise indicator of body composition changes which can be clinically useful and provide similar information obtained from more sophisticated methods. This study was designed to support or refute the reliability and validity of the BIA as a method to

monitor fluid changes in a CHF patient population undergoing diuresis.

Clinical Trials

Correlation Studies with Other Assessment Techniques

> In biological systems, electrical conduction is related to water and ionic distribution in the conductor. Because fat free mass (FFM), which includes the protein matrix of adipose tissue, contains virtually all the water and conducting electrolytes in the body, conductivity is far greater in the FFM than the fat mass of the body (Lukaski et al., 1986, 1328).

There are difficulties in applying this general principle in the complex geometry and bioelectrical characteristics that exist in the healthy human body. However, Lukaski and others have utilized this empirical relationship to develop models relating conductance to FFM, TBW, and potassium (K). In order to put this topic into perspective, correlation studies of BIA with other widely used techniques of assessment were reviewed.

Lukaski et al. (1986) compared total body water (TBW) and FFM determined with BIA to TBW and FFM

determined by D20 dilution and hydrodensitometry with total body potassium, respectively. One hundred and fourteen male and female subjects, aged 18 to 50 years, with a wide range of FFM (34 to 96 kg) and percentage body weight (4 to 41%), participated. Linear relationships were found between resistance (R) and FFM ($r = -.86$), TBW ($r = -.86$) and TBK ($r = -.79$). For males, densitometrically determined FFM was correlated highly with FFM from bioelectric impedance conductance measures ($r = 0.979$). For females, the correlation between measured FFM was also high ($r = 0.954$). Relative to hydrodensitometry, the impedance method had a lower predictive error or S.E.E. of estimating body fat than did a standard anthropometric technique (2.7 vs 3.9%). The test-retest correlation coefficient was .99 for same day single measurement and .99 for a single measurement over five days. Further investigations found high positive correlations between lean body mass (LBM) from well controlled densitometry and BIA-LBM in those with normal hydration ($r = .98$) (Lukaski, Johnson, Bolonchuk, & Lykken, 1985). The BIA also correlated well with whole body counting of TBK, and indicator of body cell mass, ($r = .96$), (Lukaski, et al., 1986).

Segal, et al. (1985) compared total body electrical conductivity (TOBEC) and BIA as methods of assessing body composition to hydrostatic densitometry, TBW by tritium (3H20) and TBK determined by 40K counting. While both methods are based on the principle that the electrical conductivity of extracellular fluid (ECF) and lean tissue is far greater than that of fat, they are conceptually slightly different. Both TOBEC and BIA were found to have similar and highly significant correlations with TBW determined by isotope dilution, LBM with densitometry. The correlation coefficient between BIA and TOBEC was highly significant (r = .903). Reliability of the BIA resistance readings were extremely stable and exhibited virtually no change within five measurements when the electrodes were kept in place. The measured resistance did not deviate from the expected values by more than + or - 2%.

The accurate assessment of TBW is necessary for the understanding of body composition. As 40 to 60% of total body mass, TBW is the single largest component of the human body. **Currently there are four methods** for the assessment of TBW: (a) the drying of carcass tissue to constant weight; (b) tissue drying from

biopsy; (c) isotope dilution and measurement and (d) electrical total body volume determinations (Twyman & Liedtke, 1987).

In isotope dilution a substance which distributes reliably in the total body volume is required. The most commonly used have been the isotopes of H20 deuterium oxide, tritium oxide, and most recently, oxygen (H2018). A tracer dose of isotopically labeled water will reach equilibrium in virtually all body water within 2 to 6 hours depending on body size of the subject and the presence or absence of hydration abnormalities. Once the equilibrium concentration is measured, the volume of dilution or TBW can be calculated (Gundersen & Shen, 1966).

A comparative study of deuterium isotope dilution (D20) versus BIA for the assessment of TBW was published by Kushner and Schoeller in 1986. A total of 58 subjects were studied. Impedance (height squared/resistance) combined with weight was able to predict the D20-TBW space with a correlation of .97 and S.E.E. = 1.75 L.

A study by Segal, Van Loan, Fitzgerald, Hodgdon, and Van Itallie (1988) reported after this study began, further validated the BIA method for body composition

estimation. At four laboratories located in four different cities in the United States, densitometrically determined lean body mass (LBMd) was compared with BIA in 1,567 adults (1,069 men and 498 women) aged 17 to 62 years and with 3 to 56% body fat. Equations for predicting LBMd from resistance measured by BIA, height squared, weight, and age were obtained. Applications of each equation to the data from the other labs yielded small reductions in correlation coefficients and small increases in SEEs. All data were pooled to derive fatness-specific equations for predicting LBMd; the resulting correlation values ranged from 0.907 to 0.952 with S.E.E. of 1.97 to 3.03 kg. To date, this is the largest study ever done and confirms the validity of the BIA method for predicting LBM in large heterogenous samples.

These studies support the claim of established reliability and validity of the BIA. A comparison of body composition data obtained from varying techniques is necessary to develop the science of body composition analysis.

> The biggest problem in doing this is that no technique has been definitively proven against cadaver or other direct analysis; therefore,

> standard methods of assessing body composition are indirect and consequently a 'true' value by which to make the comparison is not known (Twyman & Liedtke, 1987, 2).

Due to this difficulty the criteria of intake-output records and daily body weights were selected by which to compare TBW measurements taken from BIA serving as a standard of measure in a patient population. It was not technically possible at this point in time to overcome this limitation of no existing "true" value. As a result, a standard measure of test-retest and inter-investigator reliability becomes important.

Studies Performed on Various Patient Populations

A review of clinical trials performed on various potential patient populations indicated the versatility and potential of the BIA as a technique in precise assessment of body composition.

Hughes and Evans (1987) studied 36 females and 30 males (age 49 to 74 years) to determine the validity of this technique in estimating body composition in an older population. The results indicated that BIA measurements, as compared with hydrodensitometry, may

be used in a healthy, normally hydrated older population to estimate FFM.

A study by Segal, et al. (1987) assessed the distribution of body water between the body cell mass and extracellular water with the BIA. The TBW was measured with tritium dilution and ECW was measured by the radiosulfate (36S) space. Intracellular water (ICW) was calculated as TBW minus ECW. The TBW correlated with BIA resistance at $r = .92$, S.E.E. = 3.21 L. The ECW correlated strongly with BIA reactance (Xc) $r = 0.65$; $p<.0001$. Reactance was a sensitive discriminator between subjects with normal water distribution and those with abnormal overhydration. Segal et al. contend that BIA may be of value for the safe, rapid, noninvasive assessment of the distribution of TBW into the ECW and ICW compartments, and may be particularly useful in monitoring patients with obesity or other nutritional disorders which affect body water.

Schloerb et al. (1986) correlated TBW in normal humans with bioelectrical impedance. In order to consider the influence of electrolyte concentrations on BI, resistance measurements were made in vitro with varying sodium concentrations. The electrolyte

correction factor for patients with altered serum sodium concentrations were then incorporated into the analysis. Schloerb et al. concluded that BI predicts TBW, and therefore, lean body mass (LBM), body cell mass (BCM), and body fat (BF), and is a useful adjunct to nutritional assessment in surgical patients.

A study to assess body composition in amputees using BIA was conducted by Vettorazzi et al. (1987). The subjects were comprised of 24 healthy adults, 12 females, and 12 males aged 20 to 32 years. The RJL BIA-103 standard operative procedure was utilized to simulate amputations. Partial impedance was measured with various combinations: from wrist, elbow, or shoulder in the upper extremity and with ankle, knee, or hip on the lower. The researcher concluded that it is theoretically possible to apply the BIA in amputees using the partial measurements and the model developed in this study.

Molina et al. (1987) studied 41 children, aged 3 to 20 months, who were admitted to the outpatient rehydration unit of a large urban general hospital. Nineteen received oral rehydration solution, 15 received conventional intravenous fluids, and 7 received "ultra-rapid" I.V. therapy. They were weighed

and BIA was performed both before initiating hydration therapy and serially thereafter. Molina et al. concluded that BIA can detect acute increments in hydration state. Furthermore, these researchers suggested an opportunity for BIA'S use in monitoring dehydration/rehydration in young children and studying their biologic correlates in acute infantile diarrheal disease.

Spence et al. (1979) studied 10 pediatric hemodialysis patients. Bioelectrical impedance (BI) data were obtained pre-, intra-, and post-dialysis. Body weight was found to correlate well with TBW, ($r = .84$, $p<.001$). However, as in earlier similar trials with hemodialysis patients, there was a greater amount of TBW lost by BI estimation than indicated by weight loss. It was noted by the authors that radioisotope dilution studies of TBW also tend to over estimate water loss during hemodialysis.

A study of fluid retention in burn patients was carried out by Carlson et al. (1986). Subjects were 24 adult burn patients with an average age of 34.7 years, and an average of 13% surface area burned (range 3 to 50%). The fluid retained was measured by subtracting the total body water on admission from TBW after 48

hours as measured by the BIA. Recorded intake-output and estimated insensible fluid losses from the burn wound were used to determine calculated fluid retained. A comparison of BIA measurement with intake-output records showed a very strong relationship ($r = .81$, $p<.001$) between these two methods of determining fluid retention. Four patients, who sustained burns greater than 20% total body surface area, had a very strong positive association ($r = .850$, $p<.001$) between the two methods. Carlson et al. concluded that BIA is an easily performed test which gives an accurate indication of the TBW changes and net fluid retention in the burn patient. Carlson et al. concluded that net fluid retention is an accurate predictor of the extent of burn injury and mortality in burn patients.

Shellock and Amin (1986) evaluated the effects of diuretic intervention in CHF patients with the BIA. Six patients with New York Heart Association (NYHA) Class III and IV CHF were measured before and after diuresis. Ten age-matched normal subjects were measured for comparison. The TBW and percentage body water were significantly higher in the CHF patients before diuresis compared to the normal subjects. In addition, there was a statistically significant

($p<.01$) decrease in TBW and percentage body water in the CHF patients after diuresis. It is important to note that Shellock and Amin were not determining validity of BIA but only looking at data obtained by BIA. Shellock and Amin concluded that fluid changes in CHF patients treated with diuretics can be effectively monitored by BIA and could be potentially useful for guiding diuretic therapy in this patient group.

In summary, this study attempted to monitor fluid changes with BIA in hospitalized CHF patients undergoing diuresis. It was designed similar to the study by Shellock and Amin, with the exception that intake-output records and daily body weights were used as criteria by which to compare BIA measurements. These criteria were selected because they are the standard and conventional methods of assessing the fluid changes in a patient and making decisions about his status.

A shortcoming of the research on BIA is the lack of replication studies. The reliability and validity of the BIA in studies using normal healthy subjects is comprehensive. This method of body composition was bourn out of an increased interest in nutrition-obesity studies. This tool has been commercially available

only since 1982. The divergence from a healthy population to various patient populations is relatively recent and in part explains the lack of replication studies. Due to the lack of a direct measurement of body composition by which to compare the BIA, test-retest and inter-investigator reliability strategies assume a prominent role. This study utilized the idea by Shellock and Amin (1986) of evaluating diuretic intervention with the BIA, but went one step further and compared before and after measurements of BIA with before and after measurements of daily body weights and intake-output records. This addressed the inter-investigator reliability strategy. Inter-investigator reliability is defined as the degree to which two raters, operating independently, assign the same ratings for an attribute being measured. In this study, the attribute measured was total body water (TBW) as expressed in liters. The test-retest approach was satisfied by using a control group of age-matched, normal, healthy subjects and measuring their TBW two times with the BIA. This was done for two reasons: First, to document that the machine gives reliable results on the same patient and second, to establish a normal baseline.

The purpose of this study was essentially to establish the criterion-related validity of the BIA. The previous review of the various clinical trials did not substantiate enough evidence on the reliability and validity of BIA as a method to monitor fluid changes in CHF patients undergoing diuresis. This study was needed to explore this potential.

Chapter III

METHODOLOGY

A non-experimental study design was implemented to expand on the body of reliability and validity research in the use of bioelectric impedance analysis (BIA) as a method for monitoring fluid changes in congestive heart failure (CHF) patients undergoing diuresis. A criterion-related approach to assess the validity of BIA was utilized. The criteria of intake-output records and daily body weights were selected because these criteria were the standard and conventional methods utilized by nurses by which to detect fluid changes. Using a sample of 30 hospitalized CHF patients who were undergoing diuresis, the study explored the validity of BIA by comparing the TBW measured with the BIA with intake-output records and daily body weights.

The study added to the body of reliability research on the BIA using a sample of 10 healthy age-matched office patients and/or their spouses. These subjects had their TBW measured two times with the BIA. This test-retest approach was done for two reasons: first, to document that the machine gives reliable

results on the same patient and second, to establish a normal baseline.

Setting

The study was conducted at Mercy Hospital Medical Center (MHMC) in Des Moines, Iowa. Mercy Hospital Medical Center is a 500-bed community and referral hospital located in the central part of the city.

The sample was drawn from patients of a private clinical practice comprised of 10 board certified cardiologists and 6 full-time R.N.s. This group serves approximately 300 myocardial infarction (MI) patients per year, 1,200 angioplasties are performed each year, and an overall 2,005 patients are seen each year. It was estimated that 10% of these patients suffered from CHF.

Congestive heart failure patients are routinely seen by their private physicians at varying intervals. Most patients are seen monthly, although some are seen twice a month or even once a week. Routine care in this clinical practice consists of regularly scheduled physical and laboratory examinations with the patient's private physicians and additional treatment as needed,

i.e., medication adjustments, especially increase or decrease in diuretics, and possible hospital admission.

Sample

A nonprobability sampling method of selection was utilized due to the limited number of a hospitalized CHF patient population. The criteria for inclusion in the study were male and female patients who:

1. were admitted by Cardiology Associates to MHMC with a diagnosis of CHF
2. had to undergo diuretic therapy
3. were admitted between 9 a.m. and 6 p.m. Monday through Friday
4. consented to participate (Appendix A)

The stipulation of the time of admission was necessary in order to ensure that the patient was measured for TBW with the BIA prior to the administration of a diuretic. The BIA machine is owned by Cardiology Associates and was the only machine used in the study. The first 30 patients who were admitted that fit the criteria and consented to participate in the study became the sample. **This sample represents a** CHF patient population treated by physicians in a

private clinical practice admitted to MHMC in Des Moines, Iowa.

A sample of age-matched normal healthy subjects was also obtained. This sample was drawn from the outpatient clients and their spouses of Cardiology Associates.

The criteria for inclusion in this sample were male and female patients of Cardiology Associates who:

1. were in need of consultation and therefore in the office for at least one hour,
2. did not have CHF, or any symptoms of shortness of breath, angina or any other distress,
3. consented to participate (Appendix B).

A sample of 10 was obtained for this group.

Instruments

Determining if the BIA can be reliably and validly used for monitoring fluid changes in CHF patients treated with diuretics was the focus of this study. Data was collected with: (a) RJL BIA-101, (b) Health o meter portable stand-up doctor's scale (hospital bed scale only when necessary), and (c) intake-output records.

RJL BIA-101

The BIA system is conceptually an integration of electronic and computer software technologies that can be applied to body composition analysis for fluid balance monitoring, nutritional assessment, and monitoring of weight loss and gain regimes. It is a rapid, relatively inexpensive, safe, noninvasive, portable technique, which requires minimal special training of the operator and causes virtually no inconvenience to the subject. Its physical appearance is somewhat similar to that of an EKG machine but less complex.

The RJL system uses a tetrapolar electrode configuration. Electrodes are positioned in the middle of the dorsal surfaces of the hands and feet proximal to the metacarpal-phalangeal and metatarsal-phalangeal joints respectively, and also medially between the distal prominences of the radius and ulna and between the medial and lateral malleoli at the ankle. These electrodes are color coded. The subject lays fully clothed, except shoes and socks, in a supine position. A harmless 50 KHz current (800 microamps maximum) is introduced into the deep tissue of the subject via two electrodes. The second pair of electrodes measures the

electrical impedance (the RJL systems model BIA 101 has been approved by the ITT Research Institute of Chicago, Illinois, for electrical isolation safety). Using a sophisticated computer program, the system, in less than three minutes per subject, computes and generates a print-out of the following information: percentage body fat, lean body mass (LBM), body fat weight (TBW), optimal weight and body fat, and estimated basal metabolism. **According to RJL'S** scientific manual, this method is safe and precise and has only three sources of error: (a) gross misplacement of electrodes, (b) use of inappropriate electrodes, and (c) failure to collect accurate data from subject which includes sex, age, height, weight, and activity level. The portable noninvasive RJL-BIA makes accurate and convenient assessments of body composition possible in outpatient and hospitalized patients because of its easy application to any setting.

Weight Scales

A health o meter portable stand-up doctor's scale was used. Patients were weighed 24 hours after the first measurement or within close proximity thereof. The scale was checked with standard weights at midstudy

and was checked for accurate calibration each time it was used. Because there is significant variation among scales, all patients were weighed with this same scale.

Intake-Output Records

The measurement of intake-output records proceeded according to standard operative procedure of the hospital. These records were vulnerable to errors as previously mentioned in Chapter 2.

Procedures

Congestive heart failure patients admitted to MHMC between 9 a.m. and 6 p.m. on Monday through Friday were asked by the nurse making rounds with the cardiologist to participate in the study. The purpose and procedures of the study were explained to the potential subject and/or to his/her family by the nurse. A written informed consent was obtained. the nurse contacted the designated data collector who then came to the patient's bedside, weighed the patient, and took a measurement using the BIA. This methodology was repeated approximately 24 hours after the first measurement. Staff nurses of the hospital proceeded with standard operative procedure for observing and recording intake and output. The investigator

documented the intake-out records from the patient's chart as well as other necessary data (sex, age, height, weight, and activity level).

The BIA measurements from the age matched normal healthy population were taken two times. Cardiology Associates' clients and/or their spouses meeting the criteria for inclusion in this category were asked to participate and sign a consent form. A BIA measurement was taken prior to the client's consultation and again approximately one hour thereafter. This process generated the test-retest reliability coefficient. Confidentiality in data processing was ensured by using code numbers in place of the patient's name.

The investigator used three data collectors who were certified medical assistants from the Cardiology Associates practice. The three data collectors were trained individually by the dietician and a return demonstration was given several times with office personnel serving as subjects. This was done to ensure consistency and mastery of the BIA measurement technique.

Approval for this study was granted by the Human Subjects Research Review Committee of Drake University on May 18, 1988. Mercy Hospital Medical Center granted

their approval on June 16, 1988. Data collection for this study began on June 22 and ended on August 23, 1988.

Chapter IV

ANALYSIS

Introduction

In the following section, results pertaining to the validity and reliability of BIA as a method for monitoring fluid changes in CHF patients undergoing diuresis are presented. The findings will begin with a description of the physical characteristics of the sample. The validity portion of the study will then be addressed. The criterion-approach was utilized to determine validity. This is defined as the degree to which scores on an instrument (BIA) are correlated with some external criteria (DBWs and I-O). It was hypothesized that a strong positive relationship exists between BIA-TBW measurements and DBWs and between BIA-TBW measurements and I-O records. The reliability portion of the study concludes this section.

Validity Portion of Study

The physical characteristics of the subjects are summarized in Table 1. A wide range of age, differences of TBW loss, BWTs, and I-O components was

Table 1

Physical Characteristics of Subjects

	N	N*	Mean	Median	Min	Max	StDev
Age	30	0	69.87	70.00	44.00	88.00	10.76
Height	30	0	65.800	66.000	59.000	72.000	3.266
Domdiff	27	3	1.111	1.000	-1.000	6.000	1.368
Bwtdiff	30	0	0.963	0.900	-0.900	4.500	1.377
Oidiff	26	4	0.529	0.300	-1.560	3.590	1.130
Nondiff	25	5	1.080	1.000	-1.000	6.000	1.778
Domdiff2	24	3	1.250	1.000	-1.000	6.000	1.359
Bwtdiff2	27	0	1.089	0.900	-0.900	4.500	1.379
Oidiff2	24	3	0.625	0.401	-0.621	3.590	1.090
Nondiff2	22	5	1.273	1.000	-1.000	6.000	1.804
Avediff	30	0	1.100	1.000	-1.000	4.000	1.248
Avediff2	27	0	1.241	1.000	-1.000	4.000	1.235

Domdiff = change in TBW in 24 hours using measurements taken on dominant side
BWTdiff = change in BWT in 24 hours
Oidiff = change in I-O in 24 hours
Nondiff = change in TBW in 24 hours from nondominant side
Avediff = average of right and left TBWs first day minus
average of right and left TBWs second day
N = 30 17 females
13 males
N* = number of missing values

Note that all variables that end in 2 have had 3 cases (subjects) deleted; therefore, the total number of subjects for these variables is 27 rather than 30.

found. On the average, TBW loss was 1.1 L, BWT difference was 0.96 kg, and I-O difference was 0.529 L. The average age was 69. There was a total of 30 subjects, 17 females and 13 males. There were 3 subjects who were given diuretics for two days and information for both days was included in the data for this study (subjects 6 and 7, subjects 10 and 11, and subjects 15 and 16). The data were analyzed two ways, that is, using all 30 subjects and using 27 subjects (leaving out subjects 7, 10, and 16). The first day of readings was used for two of the 3 subjects (subject 6 and subject 15), but subject 11 was used rather than subject 10 because the intake-output records were not complete for subject 10.

The list of variables that were used in this analysis are described in Table 2. The first 12 variables (subject through output) were supplied on the data-collection sheets, the remaining 14 variables (dom1 through avediff) were created for use in the analysis. The BIA-TBWs were recorded for both the right and left sides of the body. Information on the dominant side of the body was collected because muscle tissue contains more water than fatty tissue and the

Table 2

List of Variables Used in Analysis

Subject	= number to identify the subject
Age	= age of subject (in years)
Sex	= sex of subject (0 = male, 1 = female)
Height	= height of subject (in inches)
Right1	= machine TBW, right side, first day (in liters)
Left1	= machine TBW, left side, first day (in liters)
Right2	= machine TBW, right side, second day (in liters)
Left2	= machine TBW, left side, second day (in liters)
Bwt1	= body weight, first day (in kilograms)
Bwt2	= body weight, second day (in kilograms)
Intake	= amount of liquids taken in 24 hours (in liters)
Output	= amount of liquids output in 24 hours (in liters)
Dom1	= machine TBW, dominant side, first day (in liters)
Dom2	= machine TBW, dominant side, second day (in liters)
Domdiff	= dom1 - dom2 (in liters)
Bwtdiff	= bwt1 - bwt2 (in kilograms)
Oidiff	= output-intake (in liters)
Nondom1	= machine TBW, nondominant side, first day (in liters)
Nondom2	= machine TBW, nondominant side, second day (in liters)
Nondiff	= nondom1 - nondom2 (in liters)
Domdiff2	= same as domdiff, subjects 7, 10, 16 deleted
Bwtdiff2	= same as bwtdiff, subjects 7, 10, 16 deleted
Oidiff2	= same as nondiff, subjects 7, 10, 16 deleted
Nondiff2	= same as nondiff, subjects 7, 10, 16 deleted
Avediff	= (average of right and left TBWs, first day) minus (average of right and left TBWs, second day); if only one side of the body was measured, that measurement was taken to be the average
Avediff2	= Same as avediff, subjects 7, 10, 16 deleted

dominant side of the body contains more muscle tissue than the nondominant side.

The variables of interest in this study are those that measure the change in body water, namely, dominant difference, nondominant difference, average difference, body weight difference, and output-intake difference. Dominant difference (domdiff) refers to the change in BIA-TBW in the 24 hours using measurements taken on the dominant side of the patient's body. When measurements could not be recorded for the dominant side the data were defined as missing. Nondominant difference (nondiff) refers to the change in BIA-TBW in 24 hours using measurements taken on the nondominant side of the patient's body and non-recorded measurements were defined as missing. Average difference (avediff) refers to the change in the average BIA-TBW (average for the right and left sides) in 24 hours. If only one side of the body was measured, that measurement was considered the average. There were no missing data associated with the variable body weight difference (bwtdiff), that is, change in body weight over the 24 hour period. If complete intake or output measurements were missing, then the variable output-intake

difference (oidiff), that is, change in amount of body water measured using intake-output records, was defined as missing.

From the composite data (Table 3) on the 30 subjects, regression analyses were conducted to determine the correlations between the variables dealing with change in BIA-TBW, change in body weight, and intake-output difference. The correlation coefficients and their associated p-values are reproduced in Table 4. From looking at this data, it is obvious that the highest correlation coefficients are recorded when the average difference (avediff) BIA-TBW data are used as shown in Figures 1, 2, 3, and 4. One of the reasons that the correlation coefficients associated with the BIA-TBW variable and dominant difference were relatively low was that there was one semi-strange value for that variable (subject 26 had a change in BIA-TBW of 6 L) shown in Figures 5, 6, 7, and 8. Interestingly, the correlations between average difference and body weight difference (Figure 1) and between average difference and oidiff (Figure 2) were larger than the correlation between bwtdiff and oidiff (Figures 9 and 10). Therefore BIA is a better match with either body weight or intake-output than the two standard methods are to each other.

Table 3

Composite Data From 30 Patients

Subject	Age/Sex	Hgt	Right 1	Left 1	Right 2	Left 2	Bwt 1	Bwt 2	In-take	Out-put	Dom 1	Dom 2	Dom-diff	Bwt-diff	Oi-diff	Non-doml	Non-dom2	Non-diff	Dom-diff2	Btw-diff2	Oi-diff2	Non-diff2	Ave-diff	Ave-diff2
1	80/0	67.0	43	*	42	*	67.6	68.1	2.457	3.450	43	42	1	-0.50000	0.993	*	*	*	1	-0.50000	0.993	*	1.0	1.0
2	68/0	68.0	*	44	*	41	65.0	62.3	*	*	*	*	*	2.70000	*	44	41	3	*	2.70000	*	3	3.0	3.0
3	80/0	68.5	45	44	44	43	93.2	91.8	1.420	1.525	45	44	1	1.39999	0.105	44	43	1	1	1.39999	0.105	1	1.0	1.0
4	71/0	68.0	46	42	44	41	74.8	73.4	1.780	2.365	46	44	2	1.40000	0.585	42	41	1	2	1.40000	0.585	1	1.5	1.5
5	86/1	65.0	26	26	25	25	44.5	43.2	1.120	2.150	26	25	1	1.30000	1.030	26	25	1	1	1.30000	1.030	1	1.0	1.0
6	70/1	65.0	37	37	36	34	83.2	81.5	2.824	3.850	37	36	1	1.70000	1.026	37	34	3	1	1.70000	1.026	3	2.0	2.0
7	70/1	65.0	36	34	35	35	81.5	81.8	3.298	1.738	36	35	1	-0.30000	-1.560	34	35	-1	--	--	--	--	0.0	--
8	68/0	70.0	45	46	43	44	86.9	84.5	1.508	3.655	45	43	2	2.40000	2.147	46	44	2	2	2.40000	2.147	2	2.0	2.0
9	67/0	72.0	44	43	45	44	85.2	85.7	1.700	1.690	44	45	-1	-0.50000	-0.010	43	44	-1	-1	-0.50000	-0.010	-1	-1.0	-1.0
10	81/1	66.0	27	28	28	28	52.7	53.6	1.210	*	27	28	-1	-0.90000	*	28	28	0	--	--	--	--	-0.5	--
11	81/1	66.0	28	28	27	27	53.6	50.5	1.390	1.550	28	27	1	3.10000	0.160	28	27	1	1	3.10000	0.160	1	1.0	1.0
12	70/1	59.0	27	27	25	26	54.1	52.5	1.949	4.575	27	25	2	1.60000	2.626	27	26	1	2	1.60000	2.626	1	1.5	1.5
13	88/1	63.0	26	25	26	25	47.3	48.2	0.927	0.900	26	26	0	-0.90000	-0.027	25	25	0	0	-0.90000	-0.027	0	0.0	0.0
14	75/1	63.0	32	*	32	*	68.0	67.5	1.255	0.675	32	32	0	0.50000	-0.580	*	*	*	0	0.50000	-0.580	*	0.0	0.0
15	71/1	66.0	45	43	39	41	101.4	97.5	3.160	6.750	43	41	2	3.90000	3.590	45	39	6	2	3.90000	3.590	6	4.0	4.0

* missing data

-- 3 cases that were removed for a portion of the analyses

Table 3 (Continued)

Subject	Age/Sex	Hgt	Right 1	Left 1	Right 2	Left 2	Bwt 1	Bwt 2	In-take	Out-put	Dom 1	Dom 2	Dom-diff	Bwt-diff	Oi-diff	Non-dom1	Non-dom2	Non-diff	Dom-diff2	Btw-diff2	Oi-diff2	Non-diff2	Ave-diff	Ave-diff2
16	71/1	66.0	39	41	39	41	97.5	96.8	3.580	3.900	41	41	0	0.70000	0.320	39	39	0	--	--	--	--	0.0	--
17	56/1	65.0	31	30	30	30	80.2	80.0	2.663	2.330	31	30	1	0.20000	-0.333	30	30	0	1	0.20000	-0.333	0	0.5	0.5
18	64/0	68.0	42	42	41	42	70.2	70.5	1.673	2.373	42	41	1	-0.30000	0.700	42	42	0	1	-0.30000	0.700	0	0.5	0.5
19	46/1	60.0	32	*	30	29	66.6	65.7	1.546	*	32	30	2	0.90000	*	*	29	*	2	0.90000	*	*	2.0	2.0
20	44/0	72.0	43	*	41	*	79.8	78.4	2.335	2.615	43	41	2	1.40000	0.280	*	*	*	2	1.40000	0.280	*	2.0	2.0
21	75/0	68.0	38	38	*	37	62.5	60.6	3.391	2.770	38	*	*	1.90000	-0.621	38	37	1	*	1.90000	-0.621	1	1.0	1.0
22	76/1	63.0	*	32	*	33	91.4	91.4	1.190	*	*	*	*	0.00000	*	32	33	-1	*	0.00000	*	-1	-1.0	-1.0
23	46/1	63.0	32	32	32	32	76.6	76.8	1.665	1.150	32	32	0	-0.20000	-0.515	32	32	0	0	-0.20000	-0.515	0	0.0	0.0
24	61/1	64.0	45	46	42	42	80.2	75.7	1.250	3.325	45	42	3	4.50000	2.075	46	42	4	3	4.50000	2.075	4	3.5	3.5
25	79/0	69.5	37	38	36	*	62.7	61.8	1.761	1.425	37	36	1	0.90000	-0.336	38	*	*	1	0.90000	-0.336	*	1.0	1.0
26	73/0	66.0	54	50	48	51	96.1	95.0	2.440	3.250	54	48	6	1.10000	0.810	50	51	-1	6	1.10000	0.810	-1	2.5	2.5
27	70/0	70.0	48	48	48	48	81.8	80.9	1.676	1.200	48	48	0	0.90000	-0.476	48	48	0	0	0.90000	-0.476	0	0.0	0.0
28	69/1	62.0	45	45	45	44	86.3	86.5	1.930	1.925	45	45	0	-0.20000	-0.005	45	44	1	0	-0.20000	-0.005	1	0.5	0.5
29	70/1	61.0	27	29	26	25	49.5	50.2	2.227	2.750	27	26	1	-0.70000	0.523	29	25	4	1	-0.70000	0.523	4	2.5	2.5
30	70/0	65.0	52	55	51	53	79.5	78.6	1.400	2.650	52	51	1	0.90000	1.250	55	53	2	1	0.90000	1.250	2	1.5	1.5

* missing data

-- 3 cases that were removed for a portion of the analyses

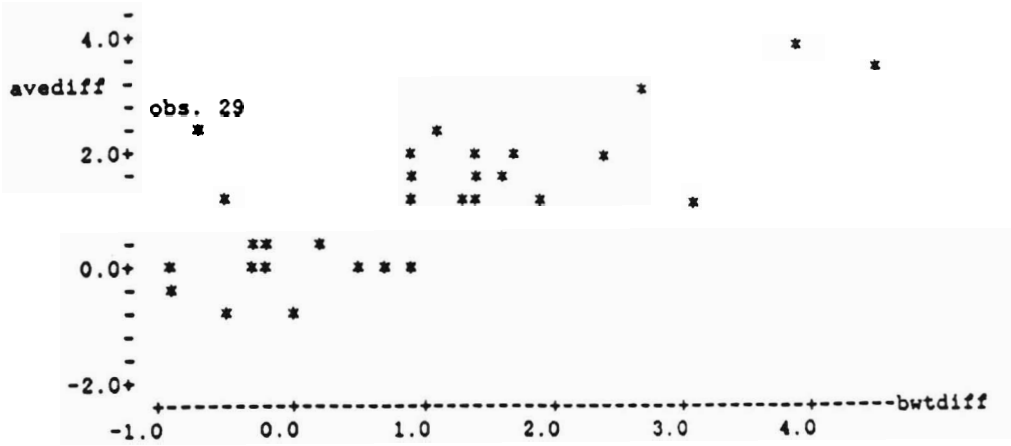
Table 4

Correlation Coefficients and p-values

No.	Variables Compared	No. of Subjects	Coefficient	p-value	No.
1	domdiff vs. bwtdiff	27	.515	.006	1
2	nondiff vs. bwtdiff	25	.648	<.001	2
3	avediff vs. bwtdiff	30	.726	<.001	3
4	domdiff vs. oidiff	25	.451	.024	4
5	nondiff vs. oidiff	22	.704	<.001	5
6	avediff vs. oidiff	26	.745	<.001	6
7	bwtdiff vs. oidiff	26	.597	.001	7
8	domdiff2 vs. bwtdiff2	24	.476	.019	8
9	nondiff2 vs. bwtdiff2	22	.622	.002	9
10	avediff2 vs. bwtdiff2	27	.701	<.001	10
11	domdiff2 vs. oidiff2	23	.477	.021	11
12	nondiff2 vs. oidiff2	20	.674	.001	12
13	avediff2 vs. oidiff2	24	.744	<.001	13
14	bwtdiff2 vs. oidiff2	24	.576	.003	14

Figure 1. AVEDIFF vs. BWTDIFF:

Change in average TBW vs. change in body weight



Correlation of avediff and bwtdiff = 0.726

p. = <.001

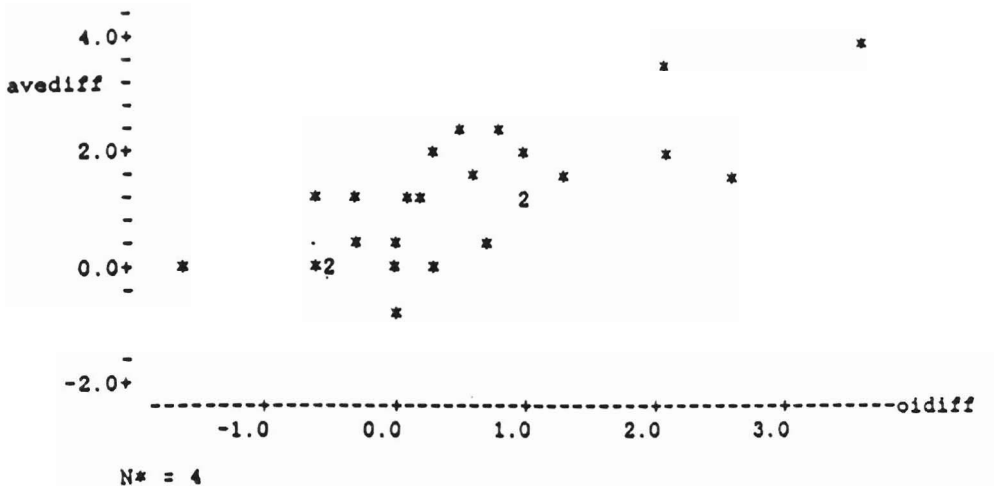
The regression equation is

avediff = 0.466 + 0.658 bwtdiff

R-sq = 52.7%

Figure 2. AVEDIFF vs. OIDIFF:

Change in average TBW vs. intake-output difference



Correlation of avediff and oidiff = 0.7456

p. = <.001

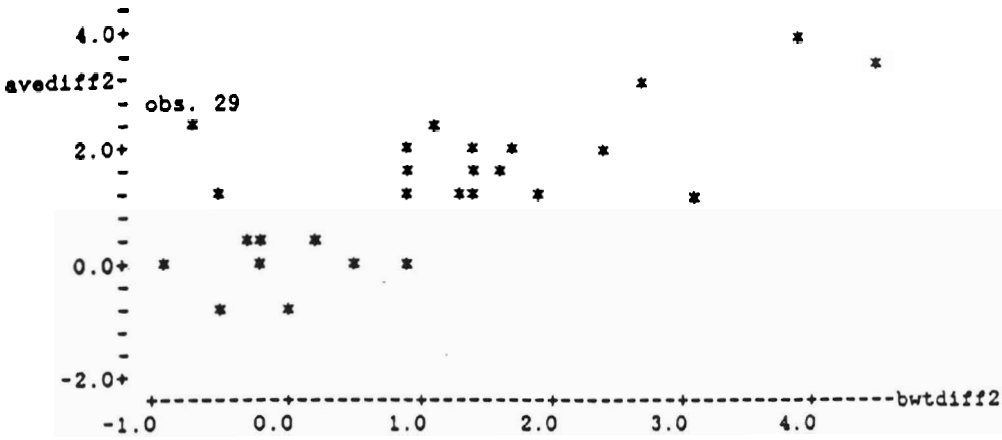
The regression equation is

avediff = 0.729 + 0.766 oidiff

R-sq = 55.5%

Figure 3. AVEDIFF2 vs. BWTDIFF2 -- deleted 3 cases

Change in average TBW vs. change in body weight



Correlation of avediff2 and bwtdiff2 = 0.701

p. = <.001

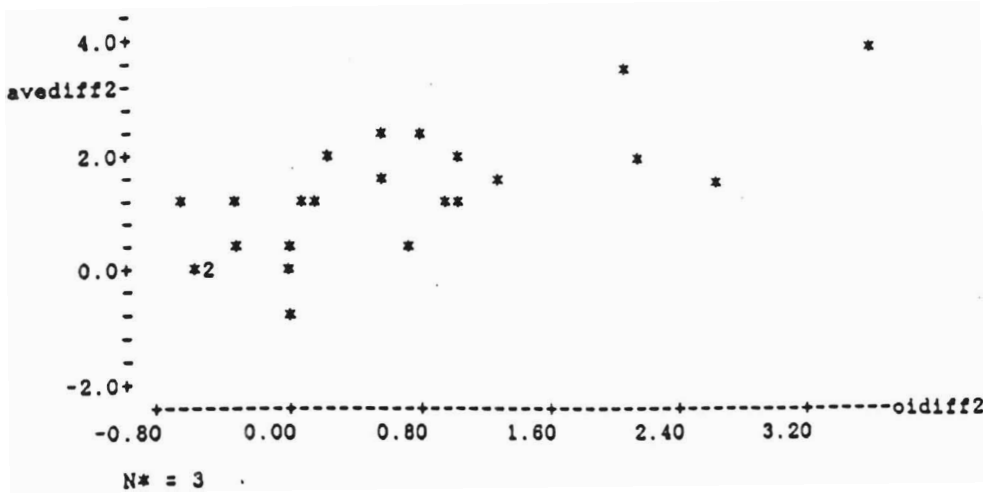
The regression equation is

averdiff2 = 0.556 + 0.628 bwtdiff2

R-sq = 49.2%

Figure 4. AVEDIFF2 vs. OIDIFF2 -- deleted 3 cases

Change in average TBW vs. intake-output difference



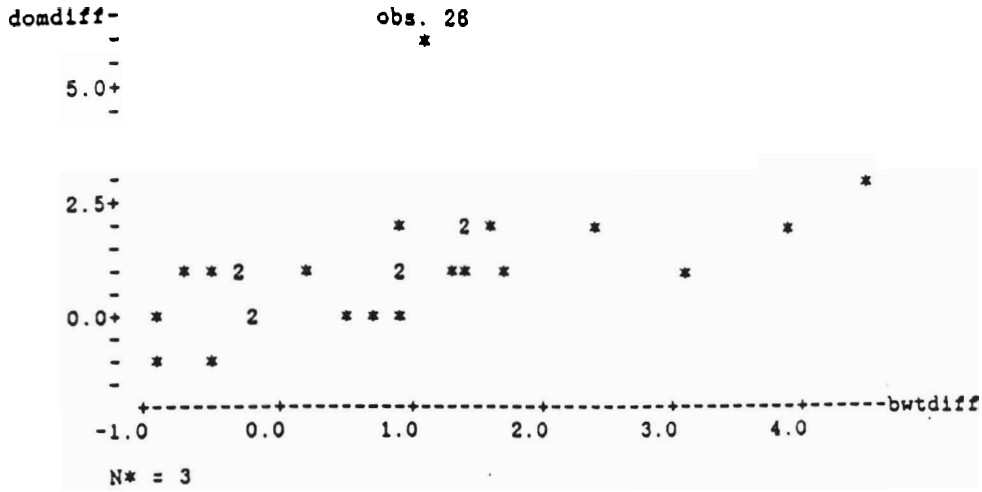
Correlation of avediff2 and oidiff2 = 0.744

The regression equation is

avediff2 = 0.734 + 0.793 oidiff2

R-sq = 55.3%

Figure 5. DOMDIFF vs. BWTDIFF: Change in TBW using dominant side vs. change in body weight



Correlation of domdiff and bwtdiff = 0.515

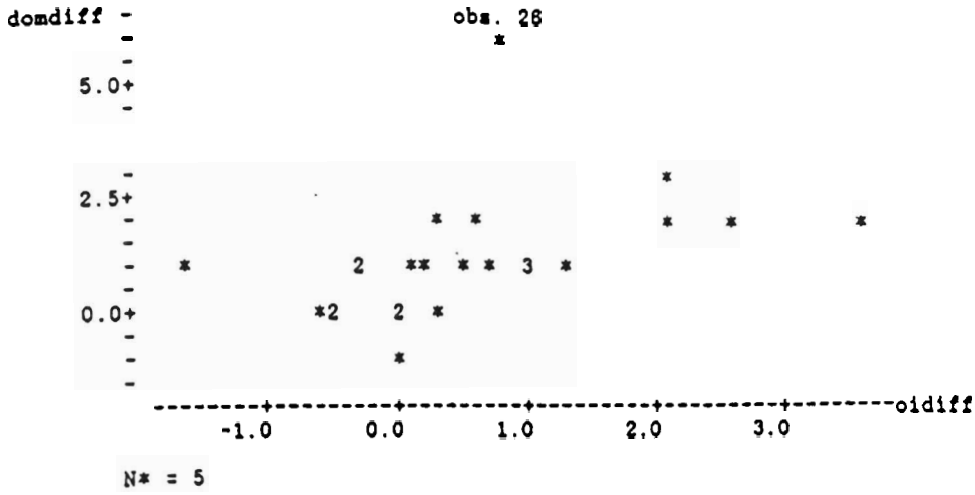
p. = 0.006

The regression equation is

domdiff = 0.6555 + 0.507 bwtdiff

R-sq = 26.5%

Figure 6. DOMDIFF vs. OIDIFF: Change in TBW using dominant side vs. intake-output difference



Correlation of domdiff and oidiff = 0.451

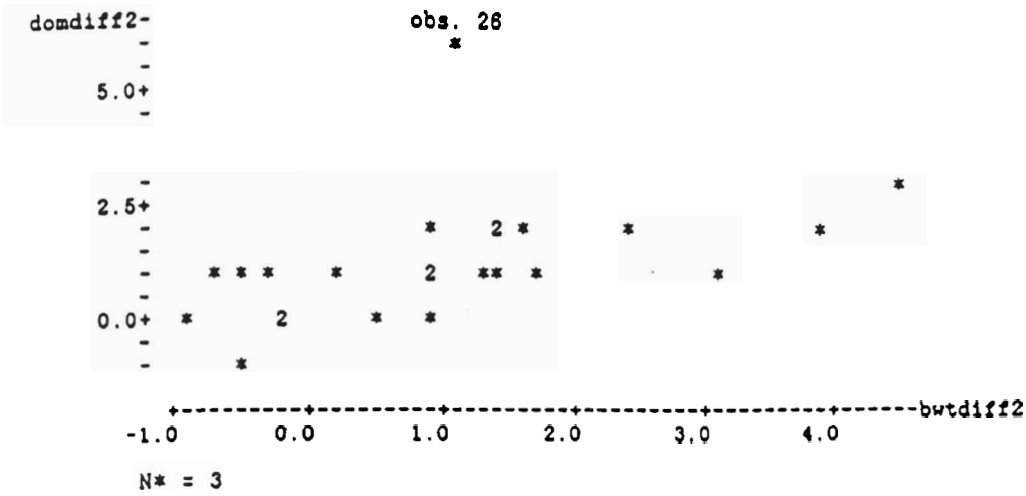
p. = 0.024

The regression equation is

domdiff = 0.851 + 0.538 oidiff

R-sq = 20.4%

Figure 7. DOMDIFF2 vs. BWTDIFF2 -- deleted 3 cases
Change in TBW using dominant side vs. change in body weight



Correlation of domdiff2 and bwtdiff2 = 0.476

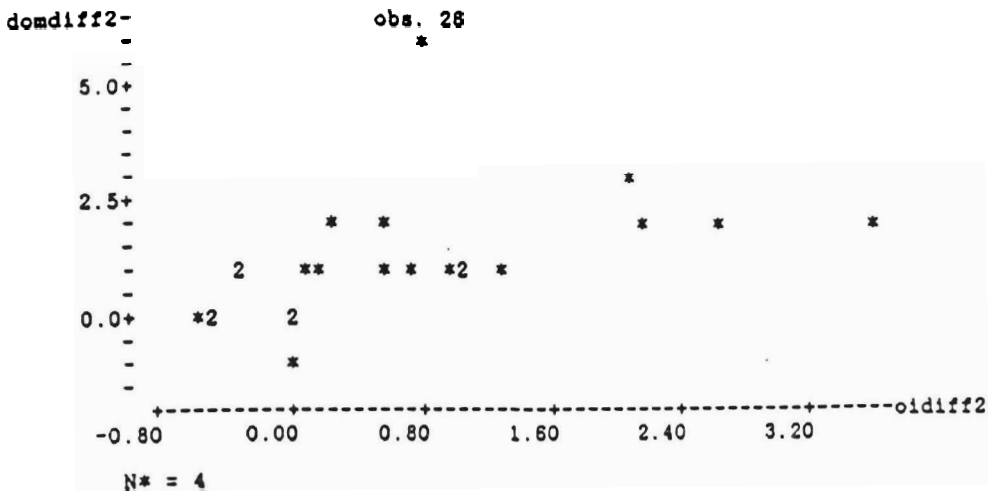
p. = 0.019

The regression equation is

domdiff2 = 0.772 + 0.463 bwtdiff2

R-sq = 22.7%

Figure 8. DOMDIFF2 vs. OIDIFF2 -- deleted 3 cases
Change in TBW using dominant side vs. intake-output difference



Correlation of domdiff2 and oidiff2 = 0.477

p. = 0.021

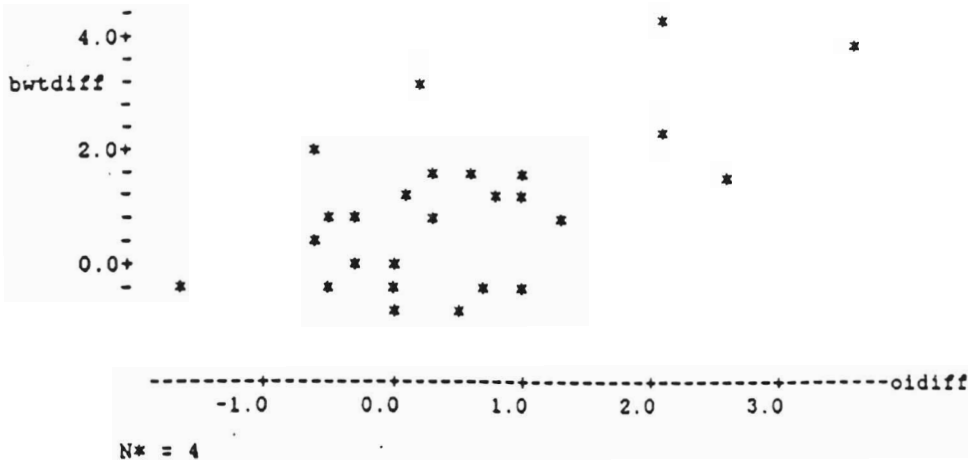
The regression equation is

domdiff2 = 0.804 + 0.610 oidiff2

R-sq = 22.8%

Figure 9. BWTDIFF vs. OIDIFF:

Change in body weight vs. intake-output difference



Correlation of bwtdiff and oidiff = 0.597

p. = 0.001

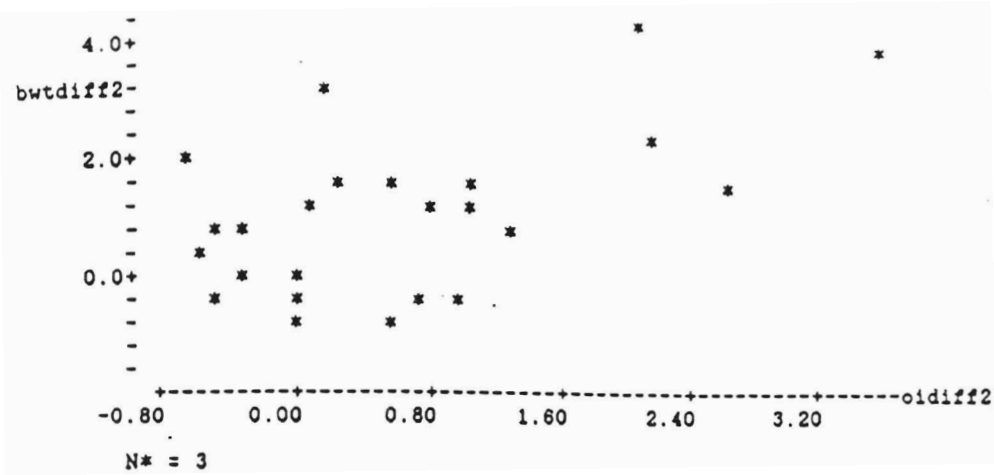
The regression equation is

bwtdiff = 0.622 + 0.729 oidiff

R-sq = 35.7%

Figure 10. BWTDIFF2 vs. OIDIFF2 -- deleted 3 cases

Change in body weight vs. intake-output difference



Correlation of bwtdiff2 and oidiff2 = 0.576

p. = 0.003

The regression equation is

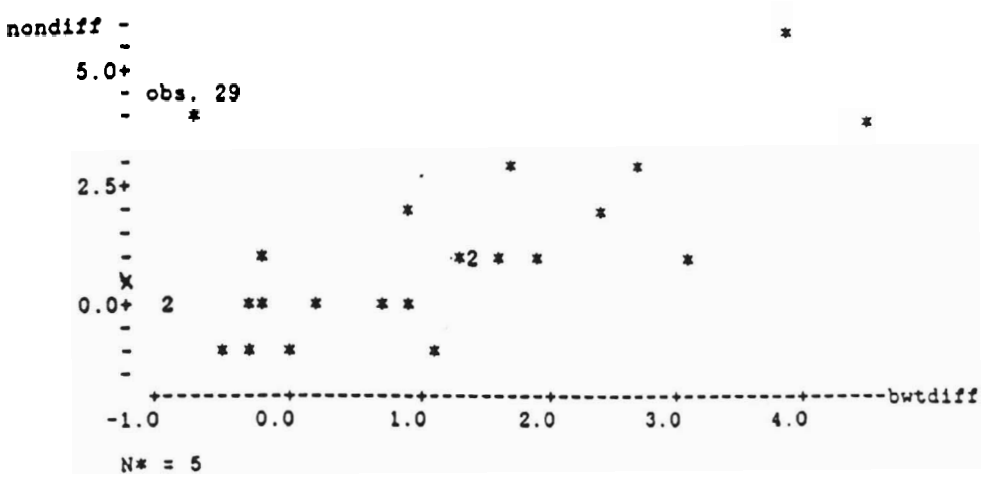
bwtdiff2 = 0.610 + 0.744 oidiff2

R-sq = 33.1%

However, it is encouraging that the correlation between body weight and intake-output was significant $r = 0.597$, $p = 0.001$.

Another potential outlier is the value for subject 29 on the BIA-TBW variable and nondiff as shown in Figures 11, 12, 13, and 14. As with the other strange value (for subject 26) this does not appear to be an "incorrect" data point, but it does not follow the pattern of the other subjects. It is important to note that when the average is used rather than the dominant or nondominant side, the strangeness associated with the observations for subject 26 and 29 disappears. The mean of two observations is less variable than the single observations; this is a characteristic that makes the mean preferable over single observations.

Figure 11. NONDIFF vs. BWTDIFF: Change in TBW on nondominant side vs. change in body weight



Correlation of nondiff and bwtdiff = 0.648

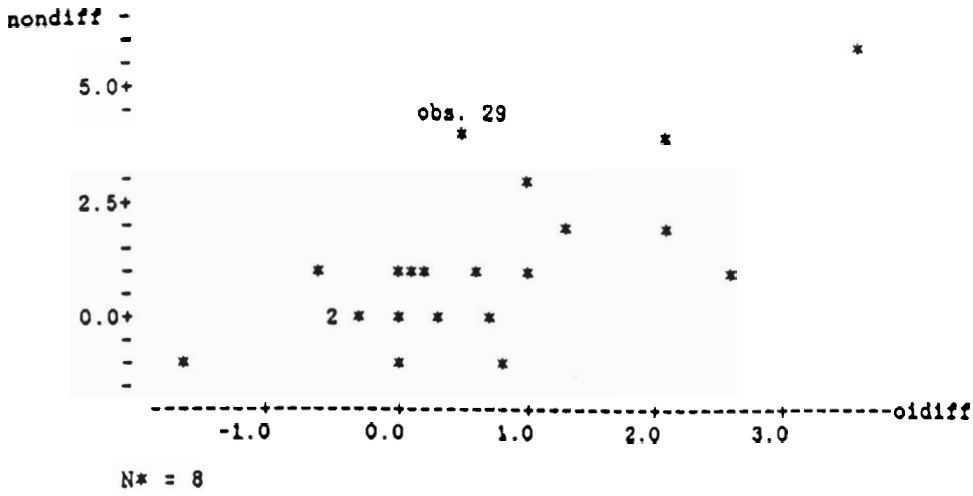
p. = <0.001

The regression equation is

nondiff = 0.278 + 0.780 bwtdiff

R-sq = 42.0%

Figure 12. NONDIFF vs. OIDIFF: Change in TBW using nondominant side vs. intake-output difference



Correlation of nondiff and oidiff = 0.704

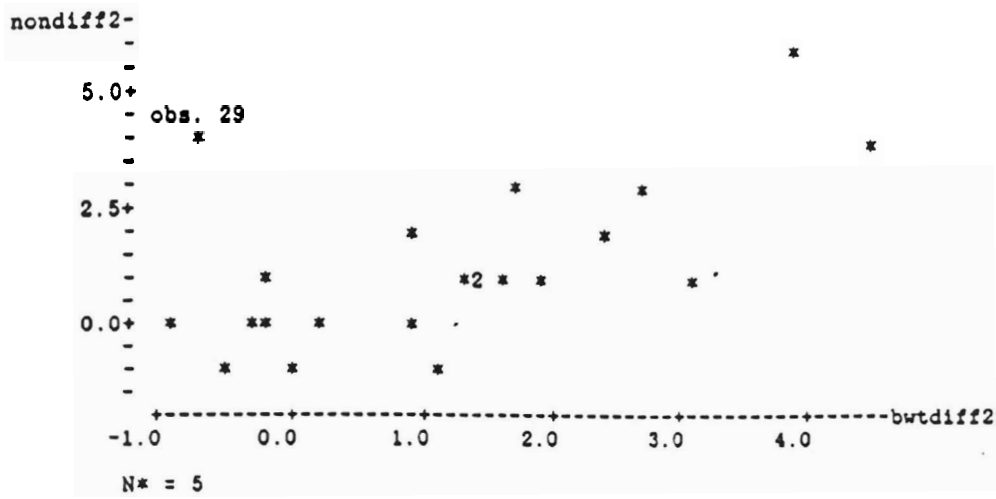
p. = <0.001

The regression equation is

nondiff = 0.493 + 1.06 oidiff

R-sq = 49.5%

Figure 13. NONDIFF2 vs. BWTDIFF2 -- deleted 3 cases
Change in TBW using nondominant side vs. change in body weight



Correlation of nondiff2 and bwtdiff2 = 0.622

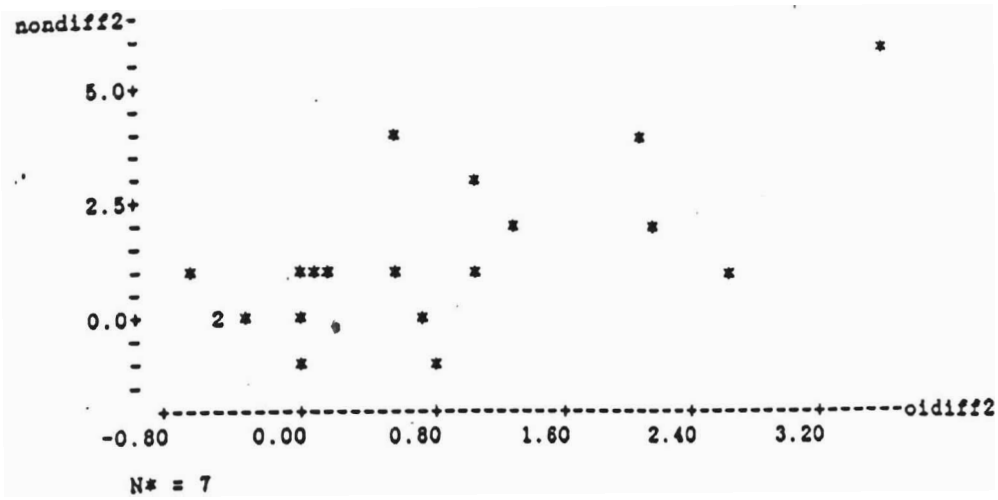
p. = 0.002

The regression equation is

nondiff2 = 0.371 + 0.757 bwtdiff2

R-sq = 38.7%

Figure 14. NONDIFF2 vs. OIDIFF2 -- deleted 3 cases
Change in TBW using nondominant side vs. intake-output difference



Correlation of nondiff2 and oidiff2 = 0.674

p. = 0.001

The regression equation is

nondiff2 = 0.516 + 1.06 oidiff2

R-sq = 45.4%

Unusual Observations

The unusual results of the observations of subjects 26 and 29 were explored further. As stated previously, observation 26 had a change in T of 6 L, a body weight difference of 1.10 kg, and an intake-output difference of only .81 L. This consistently contributed to lower correlation coefficients, especially when measuring BIA-TBW from the dominant side of the body. A review of the hospital medical records provided the following additional information.

Observation 26

This was a patient with a very complex medical history. This 73-year-old male was admitted with an acute episode of CHF. His secondary diagnoses included chronic atrial fibrillation, hypertension, chronic renal failure, liver disease, ascites, and chronic lower extremity edema requiring the use of skin grafts before for non-healing venous ulcers.

This patient is a good example of the limits at this point in time of BIA technology. First, his limbs were severely compromised and the limbs contribute to 90% of the resistance value to the reading. Second, the TBW present in the body is based on the water on

that particular side of the body and then it is assumed from that side that the other side is the same. These assumptions cannot be made in such complex disease states because different disease states carry with them different hydration states in the intracellular and extracellular compartments which can be identified by assessing cell membrane integrity. The software utilized in this study only takes into account TBW with no indication of cell membrane integrity. Last, subject 26 had significant ascites (liver was 4 cm below the right costal margin with an ascitis fluid wave present) with 4+ edema and 3 to 4+ pitting edema of the extremities. Uneven distribution of fluid will yield misleading results. It is not surprising that BIA-TBW did not correlate well with body weight changes since changes in body weight do not occur in third spacing situations such as this one.

Another piece of information produced from reviewing the chart was the difference in body weight between the hospital scale and the health o meter scale used in this study. Hospital weight recorded on day 1 of the study was 214.5 lbs. and on day 2 it was 209.25. Body weight from the study scale on day 1 was 211.5 lbs. and on day 2 it was 209 lbs. This is a

discrepancy of 3 lbs. for day one readings. It is not possible to determine who was in error on day 1. Using the hospital's recorded weights would have greatly improved the correlation. The question therefore remains: Are the results on this patient a function of a recording error or a function of a complex medical history? Subject 26 spent 11 days in the hospital, was successfully diuresed, and had lost a total of 20 lbs. at the time of discharge.

Observation 29

Subject 29 was a 70-year-old female with an admitting diagnosis of Inferior Wall Myocardial Infarction. The subject had a totally occluded right coronary artery successfully agioplastied. She entered the study on day 2 post PTCA. In addition she had pulmonary edema post catheterization and PTCA and was diuresed with IV Lasix. Secondary diagnoses included acute pulmonary edema, diuretic-induced hyponatremia, nicotine abuse, and hypertension. Subject 29 had a discrepancy in TBW loss (4 L) as compared to a body weight gain (+.70 kg) and a gain in intake-output difference (+.52 L). It is difficult to determine the reason for this discrepancy since this subject's medical history does not differ from the

sample. Most patients with CHF and in this age range have other disease entities and complications. One potential explanation is that on day 2 of the study the subject had just finished an exercise class in cardiac rehabilitation. She had not tolerated the class well and was very fatiqued. Furthermore, it is possible that the right leg was sore from the catheterization and PTCA and therefore not equally exercised as the life side--the nondominant side--which is the side of the 4 L TBW loss. Concomitantly, the right leg might have still been swollen from the catheterization trauma and thus still have an accumulation of fluid. Exercise does affect a BIA measurement.

This is but speculation since study conditions from day 1 did not remain the same for day 2. This is an example of a breach of methodology. The hyponatremia is systemic rather than regional and therefore does not offer any explanation for the one-sided difference.

It was hypothesized that there would be a strong and positive relationship between the BIA method of monitoring fluid status in CHF patients undergoing diuresis and daily body weights and intake-output

records, the standard methods of monitoring fluid status. Statistical analyses resulted in the following: avediff TBW correlated strongly with bwtdiff, $r = .729$ ($p<.001$); avediff TBW correlated strongly with oidiff, $r = .745$ ($p<.001$); nondiff TBW correlated strongly with bwt, $r = .648$ ($p<.001$); nondiff TBW correlated strongly with oidiff, $r = .704$ ($p<.001$); domdiff TBW correlated well with bwt, $r = .515$ ($p = .006$). The p-value was set at the .01 level, therefore, the above correlations support the hypothesis and outweigh the one combination that did not correlate within the p-value .01. This was the domdiff vs. oidiff, $r = .451$ ($p = .024$).

The purpose of this study is to compare measurements of TBW from the traditional nursing methods to measurements from the new method (BIA) to see how well they relate to one another. High correlations between the new method and the traditional methods does not necessarily mean that the results from the new method are correct, but it does give evidence that the new method is comparable to the traditional methods.

Reliability Portion of the Study

The results of this portion of the study indicate that estimation of TBW by BIA measurement is reproducible. The BIA measurements were obtained on 10 age-matched healthy subjects. The sample was composed of 4 men and 6 women, ages ranging from 47 to 75. The average age was 64.

Assessment of the reliability of the BIA was determined by the test-retest reliability coefficient. Data is presented in Table 5. Reliabilities were computed separately for the right and left sides of the body. The estimated reliability of two readings on the right side of the body using information from 9 healthy adults (one subject's right side was not measured because of polio) was 0.9984. The estimated reliability of two readings on the left side of the body using information from 10 healthy adults was 0.9958.

The results of this study demonstrated the reliability of the BIA method for predicting TBW in healthy middle-aged adults. These results were congruent with other studies by Lukaski (1986) and Segal (1985).

Table 5

Reliability Portion of the Study Data

Subject	Left1	Right1	Left2	Right2
1	29	29	29	29
2	44	*	43	*
3	35	35	35	35
4	28	27	28	27
5	37	36	37	36
6	45	46	46	46
7	44	43	44	43
8	39	38	39	38
9	29	29	29	29
10	42	41	41	40

Chapter V

DISCUSSION AND CONCLUSIONS

Discussion

The results of this study indicate the validity and reliability of bioelectrical impedance analysis (BIA) as an appropriate technique for monitoring fluid changes in CHF patients undergoing diuresis. The highest correlation coefficients were obtained when the average of the right and left sides of the body were used to determine BIA-TBW and then compared to body weight and intake-output records ($r = .726$, $p<.001$; .745, $p<.001$ respectively). The correlation coefficients associated with BIA-TBW obtained from the dominant side of the body were relatively low; domdiff vs. bwtdiff $r = .515$, $p = .006$ which was statistically significant and domdiff vs. oidiff $r = .451$, $p = .024$ which was not statistically significant. Correlation coefficients between the avediff and bwt and between the avediff and oidiff were both larger than the correlation obtained between bwt and oidiff ($r = .597$, $p = .001$) indicating that BIA combined with either BWT or oidiff is a better match than the two standard methods are together.

Exploration of two unusual observations identified as outliers in the sample, provided additional information that challenges the basic assumptions underlying BIA principles. The reliability portion of the study demonstrates the stability and reproducibility of BIA technology ($r = 0.9588$). Issues derived from the results of this study are the need for further and more stringent validity studies, refinement of BIA technology, and the appropriateness of using the average in patient populations.

Determination of Validity

Traditional methods utilized by nurses for monitoring fluid states in CHF patients are: (a) changes in body weight and (b) intake-output notations. Just two of the problems with these methods are that weighing an acutely ill patient may compromise an already fatigued patient, and intake-output records may be inaccurate because of missed specimens or estimation of amounts rather than exact measurement of amounts. Because of the problems associated with the traditional methods, this study looked at the BIA method for assessing amount of water lost; BIA produces measurements of TBW more directly. The most important meaning that can be assigned to the results

of this study is that using BIA in this patient population was appropriate and has significant potential. From a nursing perspective, this information offers a possibility of facilitating the assessment of fluid status. However, the high correlations between BIA and the traditional methods does not necessarily mean that the results are correct, but it does give evidence that BIA is comparable to the traditional methods.

Scientific validity is established by comparing the results from a new method with the results obtained from an already established method. The established method, also called the criterion or gold standard, has a degree of error which must be considered when interpreting the results of comparison studies. Body weight changes and intake-output differences are not considered the gold standard of fluid status assessment and the degree of error of these two methods is not known.

The reliability and validity of the criterion method in this case, body weight changes, and intake-output differences, should be assured before assessing BIA. Two factors which determine the integrity of validation studies are (a) the number and type of

subjects studied and (b) the re-test reliability of both the new and standard methodologies. This study can be considered a study that tested the idea of monitoring fluid status of CHF patients with BIA, and comparing these measurements with nursing assessments of the patient's fluid status. The study confirms that the idea was appropriate and deserves further and more stringent scientific investigation.

Refinement of BIA Technology

The BIA method is based on the principle that impedance to the electrical flow of an injected current is related to the volume of a conductor (the human body) and the square of the length of the conductor (height-squared) (Nyboer, 1970). Hoffer, Meador, and Simpson (1969) demonstrated that TBW and lean body mass (LBM) were strongly correlated with ht2/resistance, where body resistivity or impedance was measured with a tetrapolar configuration. The living organism contains intracellular and extracellular fluids that behave as electrical conductors and cell membranes that act as electrical condensers. Thus body fluids and electrolytes are responsible for electrical conductance and cell membranes are involved in capacitance. As mentioned previously, reactance is a

measure of the quantity of cell membrane capacitance and indication of the quantity of intracellular or body cell mass. However, the human body is not a simple geometrical conductor and the application of the bioelectrical impedance principles to situations of complex medical histories is challenged. For example, the current software used assumes a symmetrical distribution of body fluids, and thus the effects of unequal fluid localization such as ascites or hydrothorax are not distinguished. A BIA-TBW may show a significant water loss when, in fact, there has been a shift of fluid to the abdominal cavity. In different disease states, hydration abnormalities are present. This factor requires serious consideration both in terms of electrode configuration and equations used in the software.

The current software utilizes only the resistance value in the equation. For general adult populations the resistance measurement is sufficient, but this does not apply to patient populations. Reactance measurements are required to detect the hydration abnormalities and rapid changes in body composition which frequently occur in illness. Changes in the body composition can be disproportionate in illness. Large

accumulations of ECM as fluid often occur due to the breakdown of cell membrane barriers. The sensitivity of reactance to changes in the cell membrane make it crucial for the assessment of ICM, ECM, and BF components of body composition. Whereas resistance can be equated to the TBW volume (ICM + ECM), reactance can be equated to the quantity of cell membrane barriers which separate the intracellular and extracellular volumes. In a telephone conversation in July 1988 D. Twyman reported that a new software is currently being developed that will incorporate the reactance value in the equations which is then meant to distinguish extracellular water changes vs. intracellular water changes by assessing the integrity of the cell membrane. With the reactance variable added, shifts from one compartment to another might be identified. Disease entities such as CHF, renal disease, and other chronic illnesses require methods sensitive to changes in the distribution of TBW, intracellular mass and extracellular mass. In spite of the chronic and complex medical histories of the sample used in this study, fairly good correlations were obtained and adds credibility to the BIA potential as an accurate and timely methodology for fluid assessment.

Identification of unusual observations which alerted this investigator to the limitations of BIA technology was an important finding of this study.

Using the Average

Taking the average of the right and left sides of the body resulted in higher correlations between BIA-TBW and body weight and intake-output records. This combination was a better predictor of TBW when compared to BWT and I-O records. This investigator believes that this maneuver is justifiable. There are many unknown variables that could affect a BIA-TBW measurement. For example, laying in bed on one side for prolonged periods could affect body fluid accumulation. The use of a cane means that there is a better developed side inferring more muscle mass and therefore more TBW on that side. Other examples could include hemiplegia remnant from a stroke or arthritis. Any condition that exaggerates one side of the body over the other justifies taking the average. It is important to remember that the recorded BIA-TBW is based on the water on the particular side of the body measured and it is assumed that the other side is the same. Chronic illnesses are too impairing in known and unknown ways and therefore taking the average

offers a more balanced assessment. This was a meaningful finding because taking the average was not mentioned in any of the previous literature.

Limitations

The limitations of the study are as follows:

1. Body composition analysis techniques used as criteria by which to compare the BIA have all been indirect methods of assessment. Cadaver dissection and tissue analysis provide the only direct measure of body composition in man. Lacking a "true" value for body composition data imposes a degree of uncertainty on the validity of BIA.

2. The assessment of body composition with bioelectrical impedance is most accurate in those subjects with normal hydration, as are all estimates of body composition derived from TBW. Biological errors such as interindividual deviations from basic assumptions are present but cannot be controlled. This study used a critically ill patient population and though a few clinical trials suggested that monitoring fluid status with the BIA is appropriate and accurate, not enough is known about the breakdown of cell

membrane barriers that occurs when there is a large accumulation of extracellular fluid.

3. The process of obtaining body weights from one day to the next and maintaining an accurate intake-output record was vulnerable to errors and did impact on the correlation. **The focus of the study was to** determine the reliability and validity of the BIA comparing it to the standard and conventional methods of assessing fluid status, specifically, DBW and I-O. These external criteria were obtained as precisely as possible.

4. The reliability and validity of the standard methods were not obtained and therefore, diminish the integrity of this validity study. However, this study fits the concept of a pilot study better because it tested an idea and used a small sample.

5. Due to the newness of BIA technology, the equations of the software and electrode configuration used for this study were developed from healthy populations. It is encouraging that statistically significant correlations were nevertheless obtained.

6. Generalizability is limited due to the small sample and because a sample of convenience was used. However, it would be unrealistic to expect any other

kind of sample because of the disease-specific criteria. Therefore, the results of this study should only be applied to patients of this private clinical practice at this time.

Future Research and Implications for Practice

Most of the research reviewed in this paper acknowledged that additional studies are required to establish the validity and reliability of the bioelectrical impedance method. Studies are needed in critically ill patient populations, particularly those who have alterations in body water distribution and electrolyte compositions. This study was a beginning effort in assessing the specific patient population of CHF subjects. Replication studies in this area are in order and are appropriate for nursing research. For example, a patient population of renal dialysis patients offers more meticulous monitoring of fluids during the procedure by which to compare the BIA-TBW.

The development of equations for specific disease entities is the method for improved predictability of BIA-TBW. This is a process that should be undertaken by experienced researchers. After numerous specific patient populations are measured, prediction equations

should be developed, cross validated for that population, and then incorporated into the BIA software.

Determination of validity is a long and tedious but necessary methodology. The potential of the bioelectrical impedance technique appears to be unlimited because it is software driven. It is a matter of finding optimal equations and electrode configuration for specific patient populations. Nurses can make important contributions to this area by designing research in their specialty, using BIA as a method of monitoring their patients' fluid status. This procedure is painless and efficient enough to incorporate into their patient's daily care.

Studies demonstrating the reliability and validity of BIA on normal healthy subjects are comprehensive and scientifically based and substantiate enough evidence to suggest the appropriateness of the BIA method as a reliable and valid technique in assessing various patient populations. By comparing the BIA method with the already acceptably reliable and valid methods of DBW and I-O records utilized by nurses, this study showed that the BIA method is at least as reliable and valid as the standard methods currently used.

The implication for nursing practice is to provide a rapid and precise fluid assessment tool for both the nurse's convenience and the patient's comfort. It is recommended by this investigator that, at this point in time, this technique be used as an adjunct in fluid assessment in specialty units such as renal dialysis units, intensive care units, and cardiac rehabilitation units. Another implication of this study is that it has demonstrated that the continued advancement in technology offers nurses innovative opportunities to upgrade the quality of nursing decision-making and therefore, upgrade the quality of nursing care.

The application of this study is not of immediate clinical relevance. The BIA method cannot replace the standard fluid assessment methods currently utilized by nurses. The statistically significant positive correlations obtained in this study offer encouragement that in the future with further refinement, this method could very well replace the standard methods. Nurses may feel well assured that for now, the current methods are optimal.

Bioelectrical Impedance Analysis is a rapid, noninvasive, and convenient method for the estimation of TBW that appears appropriate for fluid status

monitoring of CHF patients undergoing diuresis. However, further research is needed to determine the sensitivity of BIA to detect changes in fluid shifts that may occur during diuresing and other situations associated with complex medical histories. This study has contributed to the small body of reliability and validity studies of the BIA method of fluid monitoring in a patient population.

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APPENDIX A

Consent Form

Consent to Be a Research Subject

A study is being done by D. Iannone, R.N., a graduate student at Drake University, to learn more about monitoring the fluid changes that occur when diuretics are taken.

A new device called the Bioelectrical Impedance Analyzer (BIA) has been developed. One of its functions is to measure a person's total body water (TBW). It is thought that its precision and accuracy is as good if not better than standard methods of monitoring fluid changes, specifically, weighing patients and recording their intake and output. The BIA method offers a rapid, noninvasive, and precise means of assessing total body water.

Because you are going to undergo diuretic treatment you have been asked to be in this study.

If you agree to participate, the nurse will ask you to empty your bladder and then to lie down on your back while she applies two electrodes to your wrist and two electrodes to your ankle (like is done for a cardiogram). A harmless current will be introduced into the deep tissue via the electrodes. The machine will then record results. This process will take less than three minutes and all you need do is lay quietly on your back. You will feel no discomfort or any sensation. This process will occur on admission prior to receiving diuretic medication and twenty-four hours thereafter. The investigator will obtain data about your daily weight and intake-output record directly from your chart.

This study will entail making a comparison of the BIA of total body water with your daily body weight and your intake-output record which indicates how much water you have lost since taking the directic. It is thought that the BIA will correlate highly with changes in your weight and changes in your intake-output record. Though this study will not benefit you directly at this time, you will be making a contribution to the knowledge base of fluid monitoring, which may help care for patients like yourself more efficiently in the future.

All data obtained on you during the course of this study will be kept confidential and accessible only to the principal investigator and her assistants on this study. If you have other questions you may call Ms. Iannone at 288-8100 or 288-8574.

Alternatives

The alternative to participation in this study is monitoring of fluid changes with the standard methods of weighing and recording intake and output of fluids.

Voluntary Participation

Participation in this study is voluntary. No compensation for participation will be given. I understand that I am free to withdraw my consent to participate in this treatment program at any time without prejudice to my subsequent care. Refusing to participate will involve no penalty or loss of benefits to which I am otherwise entitled. **I am free to seek care from a physician of my choice** at any time. If I do not take part in or withdraw from the study, I will continue to receive care.

Confidentiality

The confidentiality of information concerning my participation in this study will be maintained whenever possible. This information may be disclosed to other physicians and researchers and may be published as research. Any published material will not identify me by name. My medical records may be examined by representatives of the food and drug administration.

I have read all of the above, asked questions, received answers concerning areas I did not understand, and willingly give my consent to participate in this program. Upon signing this form, I will receive a copy.

_____ _____

Subject's Signature Date

_____ _____

Witness's Signature Date

_____ _____

Investigator's Signature Date

APPENDIX B

CONSENT TO BE A RESEARCH SUBJECT

Consent to be a Research Subject

A study is being done by D. Iannone, R.N., a graduate student at Drake University, to learn more about bioelectrical impedance analysis (BIA), a new technology that determines a person's body composition such as body fat, lean body mass, and total body water.

One of the purposes of this research study is to determine if the BIA machine gives reliable results on the same patient and to establish a normal baseline.

Because you are currently not experiencing any chest pain, shortness of breath, edema, or any other symptoms that suggest that you have excess water, you are being asked to be in this study.

If you agree to participate, the dietician will ask you to lie down on your back while she applies two electrodes to your wrist and two electrodes to your ankle (like is done for a cardiogram). A harmless current will be introduced into the deep tissue via the electrodes. The machine will then record results. This process will take less than three minutes and all you need do is lay quietly on your back. You will feel no discomfort or any sensation. This process will occur prior to your consultation with the dietician and afterwards. During this consultation (1-2 hours) you are asked not to eat, drink, or smoke.

This part of the study will entail making a comparison of your first BIA measurement with the second BIA measurement. It is thought that the first BIA measurement will correlate highly with the second BIA measurement. Though this study will not benefit you directly at this time, you will be making a contribution to the knowledge base of BIA, which may help care for patients like yourself more efficiently in the future.

All data obtained on you during the course of this study will be kept confidential and accessible only to the principal investigator and her assistants on this study.

Participation in this research is voluntary. You have the right to refuse to participate and the right to withdraw later without any jeopardy to your care.

_____ _____

Date Subject Signature

_____ _____

Date Dietician Signature

APPENDIX C

Reliability Data Collection

Reliability Data Collection

Code Number_____

Name_____

Date_____

Age_____

Sex_____

Height_____

Weight_____

Activity_____

Time_____	Resistance (R)		Reactance (Xc)		TBW (L)
	R	Ohms	R	Ohms	L
	L	Ohms	L	Ohms	

Time_____					
	R	Ohms	R	Ohms	L
	L	Ohms	L	Ohms	

APPENDIX D

Validity Data Collection

Validity Data Collection

Code Number _____

Pt. Name _____

Room _____

Age _____

Ht. inc. s _____

Sex _____

Activity _____

1st Day

Consent form _____

Void prior to wt. & BIA _____

Calibrate Scale _____

HOB _____

Electrode Placement _____

(Cut edges up, tabs on same side, red wires & leads to head)

Body parts not touching _____

Clothing/monitors _____

Diuretic _____ Time given _____

I & O ordered _____

RA _____

2nd Day

Copy given to pt. _____

Void prior to wt. & BIA _____

Calibrate Scale _____

HOB _____

Electrode Placement _____

Body parts not touching _____

Clothing/moitors _____

I & O obtained _____

RA _____

Admission

Date _____

Time _____

Resistance (R)		Reactance (Xc)		TBW	BWT
R	Ohms	R	Ohms	R	lb.
L	Ohms	L	Ohms	L	kg.

24 hrs. p

Date _____

Time _____

Resistance (R)		Reactamce (Xc)		TBW	BWT
R	Ohms	R	Ohms	R	lb.
L	Ohms	L	Ohms	L	kg.

I =

O =

Return this form to Bev each time.